Asian Biotechnology and Development Review (ABDR) is a peer reviewed, international journal on socio-economic development, public policy, ethical and regulatory aspects of biotechnology, with a focus on developing countries. ABDR is published three times a year with support of Department of Biotechnology, Government of India and UNESCO by Research and Information System for Developing Countries (RIS), a New Delhi based autonomous think-tank, envisioned as a forum for fostering effective policy dialogue among developing countries on international economic issues.

Innovation, Intellectual property rights and controversies over GM crops are important themes in debates on biotechnology and development. Articles in this issue address the different dimensions in these topics. The articles discuss the changing contours of innovation in biosciences in US, Europe and Asia and their implications; relevance of open source approach in biotechnology and bioinformatics; the applicability of the contested idea of planned obsolescence to Bt cotton; and developing a model to frame and understand controversies over GM crops in India.

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2. Manuscripts should be prepared using double spacing. The text of manuscripts should not ordinarily exceed 7,000 words. Manuscripts should contain a 200 word abstract, and key words up to six.

3. Use ‘s’ in ‘-ise’, ‘-isation’ words; e.g., ‘civilise’, ‘organisation’. Use British spellings rather than American spellings. Thus, ‘labour’ not ‘labor’.

4. Use figures (rather than word) for quantities and exact measurements including percentages (2 per cent, 3 km, 36 years old, etc.). In general descriptions, numbers below 10 should be spelt out in words. Use thousands, millions, billions, not lakhs and crores. Use fuller forms for numbers and dates—for example 1980-88, pp. 200-202 and pp. 176-84.

5. Specific dates should be cited in the form June 2, 2004, for example ‘the eighties’, ‘the twentieth century’, etc.

References: A list of references cited in the article and prepared as per the style specified below should be appended at the end of the article. References must be typed in double space, and should be arranged in alphabetical order by the surname of the first author. In case more than one work by the same author(s) is cited, then arrange them chronologically by year of publication. All references should be embedded in the text in the anthropological style—for example ‘(Hirschman 1961)’ or ‘(Lakshman 1989:125)’ (Note: Page numbers in the text are necessary only if the cited portion is a direct quote). Citation should be first alphabetical and then chronological—for example ‘Rao 1999a, 1999b’. More than one reference of the same date for one author should be cited as ‘Shand 1999a, 1999b’.

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Editorial Introduction

K. Ravi Srinivas*

The contents of this issue deal with challenges in bio-innovation in Europe and Asia, the question of using open source models in biotechnology and bioinformatics, the relevance of the concept of planned obsolescence in debates in agricultural biotechnology and developing a model to frame and understand controversies over GM crops in India. The two book reviews examine recent publications on Socio-Economic Assessment of Bt cotton in India. Certainly, these articles and reviews cover topics that are of interest to anyone following developments in biotechnology and their impacts on society. As a journal Asian Biotechnology and Development Review (ABDR) has strived to publish views and articles that are based on informed positions backed with data and analysis, articles that are shorn of rhetoric and bring more light than heat to debates and controversies.

In the ever changing world of biotechnology, technological developments bring in new questions and challenges for regulation and governance. In case of biotechnology regulation, technologies like genome editing pose new challenges not only for regulators but also for society. With this in mind we intend to expand our coverage to emerging issues and emerging technologies like synthetic biology and also the bio-nano convergence. The recent debates over genome editing, germline modification and ‘3 parent babies’ indicate that addressing Ethical, Legal and Social Issues is inevitable and only a better interaction among scientists, industry and society will result in better understanding of the positions of different stakeholders, their aspirations and fears and the values that drive their positions. ABDR will contribute to informed debates and dialogues on technology, nature and society. In this, ABDR will draw upon RIS work programme on Science, Technology and Innovation and also the various initiatives of UNESCO on S&T and governance.

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The International Editorial Board members have over the years helped *ABDR* in finding its direction and their support in many ways has made *ABDR* a better journal. We thank them for their encouragement and engagement with the journal. No journal can survive this long without authors and peer reviewers. We express our gratitude to the authors who have made *ABDR* a remarkable journal and to the reviewers whose contributions have enabled in improving the quality of the articles. Finally, a Big Thanks to the readers whose support has been a source of strength to us.

With this issue *ABDR* completes 16 volumes and steps into seventeenth volume. The first issue was published in October 1997. Since the first issue *ABDR* has come a long way. Although the title indicates Asian the coverage has been global. In the recent years we have been endeavoring to publish contributions from Africa, Europe, South America, US and Canada. In the coming year *ABDR* will cover new themes and issues, more through Special Issues and also through articles and opinion pieces. The global coverage will be further strengthened and the contents will reflect this.

I take this occasion of completion of 16 volumes to thank all those who have made this possible through their continued support and encouragement. *ABDR* is housed at RIS and the Director Generals of RIS have been constant source of support for *ABDR*. The current Director General of RIS himself has a long association with *ABDR* since its inception and is also one of the founders of *ABDR* is support, opinions and views would definitely be an asset to *ABDR*. Publication Officer and his team have been a great support. UNESCO has been supporting *ABDR* for many years both in terms of financial support and editorial support. Working with UNESCO has been mutually beneficial and we are grateful to UNESCO for their continuous support over the years. Department of Biotechnology, Government of India is another source of support for *ABDR*. We thank the Department of Biotechnology for their sustained support to our efforts.

We look forward to receiving your views, opinions and suggestions and seek your continued support to the journal.
Divergence, Convergence, and Innovation: East-West Bioscience in an Anxious Age

William Hoffman* and Leo Furcht**

Abstract: If current economic growth trends persist, the “Great Divergence” between Western Europe and East and South Asia in per capita income that commenced two hundred years ago will close sometime this century. Key to the closing will be greater accessibility to technology and higher education in East and South Asia and the relentless diffusion of knowledge including in the biosciences. Advances in the biosciences are poised to contribute in a major way to Thomas Malthus’s four necessities of human life – food, fiber, fuel, and building materials – as well as to human and animal health, biodiversity conservation, and environmental remediation and sustainability. Powerful new biological technologies like genomics and synthetic biology are just beginning to be applied in ways that can sever the link between economic growth and carbon pollution. Precise genomic editing of cereal grains could equip rice, wheat, and maize with nitrogen fixation capabilities, thus reducing the need for synthetic fertilisers with their environmental and atmospheric costs. East and South Asia, facing major food production challenges, ecological limits, pollution from fertiliser use, and drought from climate change, may take the lead over the West in adopting innovative food crop technologies.

Keywords: bioscience, innovation, energy, ecosystems, genomics, GM crops

Two centuries ago Britain and Western Europe began to leave the rest of the Eurasian continental landmass behind in per capita income (Maddison 2006). Historian Kenneth Pomeranz called the phenomenon that separated Europe from China economically the “Great Divergence” (Pomeranz 2000). He borrowed the term from political scientist and historian Samuel
P. Huntington who used it to illuminate how the Western world overcame pre-modern economic growth constraints and surged ahead of the East beginning in the nineteenth century.

Some scholars, Pomeranz included, attribute the divergence to colonialism, intercontinental trade, and especially energy production from the burning of Carboniferous biomass in the form of coal, which was plentiful in England’s West Midlands where the Industrial Revolution began. Pomeranz reminds us that technological innovation and economic development occur in an ecological context. He takes into account the exploitation of land-based biosystems for food, fiber, fuel, and building materials production – English economist Thomas Malthus’s four necessities of life, which were in competition with each other for land – and the ecological constraints to economic growth such exploitation posed. Colonial resources and conveniently located coal served to alleviate these ecological constraints in Britain and set the country on a path of scientific and technological advance with supportive social and political institutions for entrepreneurs.

Environmental history is one of the fastest growing sub-disciplines of the field (Burke 2009).\(^1\) It is destined to become more important with the growing environmental consequences from massive extraction and burning of fossil fuels, the damming of rivers, deforestation, and the production and use of nitrogen-based fertilizers and cement. “If the eighteenth century pushed the limits of the biological old regime, the nineteenth century and especially the twentieth century shattered them” (Pomeranz 2009).\(^2\) The biological new regime, as Pomeranz describes it, is distinguished by half of the growth in the human population occurring in the past thirty years, half of all net water withdrawals in the past fifty years, a fifteen-fold increase in annual energy consumption since 1900, and unprecedented environmental degradation and adverse impacts.

Twenty-first century history, when it is written, will further entwine the economic and ecological storylines of the human experience. It will also provide a bookend for the “Great Divergence” of the previous two centuries, given current global trends in economic growth, advanced education, and technological innovation (Dervis 2012). The world economy’s center of gravity has been migrating eastward for three decades, reflecting rapid growth in incomes of the vast populations of China, India, and the rest of
East and South Asia (Quah 2011) and producing anxiety in the West over its eroding economic leadership since 1980. The gradual convergence in East-West per capita income, uneven as it is,\(^3\) will continue to be influenced by trade, capital investment in the East, the rapidly emerging Asian middle class, and the East’s greater accessibility to higher education and technology than ever before. Technological convergence among nations and between different parts of the world may be abetted by free trade and foreign direct investment, but it is fundamentally a process of the diffusion and sharing of knowledge – “the public good par excellence” (Piketty 2014).

Environmentally sustainable economic growth will require putting knowledge of life code, cellular processes, biosynthesis, and biological regeneration to practical use. The biosciences are in the midst of a convergence of their own – with information technology, nanotechnology, microelectronics, materials, artificial intelligence, robotics, architecture, and design. The field is poised to contribute in a major way to Malthus’s four necessities of human life – food, fiber, fuel, and building materials (bio-based construction materials). That will occur on top of the contribution of the genomic science, molecular and synthetic biology, regenerative medicine and other biological technologies make to human and animal health, biodiversity conservation, and environmental remediation and resilience (OECD 2009; Chaturvedi and Srinivas 2014; Hoffman and Furcht 2014; Hoffman 2014).

Technological innovation is responsible for more than half of the growth in advanced economies by most accounts.\(^4\) Though biotechnology was pioneered in the West, today it is a global enterprise, with major hubs in China, Hong Kong, India, Japan, Singapore, South Korea, and Taiwan in addition to Europe, the Americas, and Australia (Hoffman and Furcht 2014). The future distribution of entrepreneurial bioscience will depend on the forces of technological innovation, urbanisation, globalisation, and research investment. These forces are overcoming the historic inability of developing countries, many of them in East and South Asia, to adopt new technologies and employ them efficiently to achieve economic productivity gains (Clark and Feenstra 2001; Dabla-Norris et al. 2013). But productivity gains in and of themselves are not enough. Achieving them through more efficient energy use will be essential to reduce the burden fossil-fuel combustion places on natural biosystems and the environment, a burden
that pulls investment and energy away from producing goods and services to abatement and cleanup activities and pollution-related health care (Laitner 2013). The economic impact of Anthropogenic climate change, the “ecological bill” for the “Great Divergence,” makes forecasting economic growth increasingly precarious.

Biology has been called “the biggest science,” with the most scientists, the most funding, the most scientific results, the most ethical significance, and where there is the most to learn given its billions of years of experimental results involving self-replicating organisms (Kelly 2006). The “bioeconomy” can be understood as the set of economic activities relating to the invention, development, production and use of biological products and processes (OECD 2009). An emerging bioeconomy across Eurasia and around the world will mark the century ahead. As developing economies become wealthier they contribute in an ever-larger way “to pushing the technological frontier forward,” say US Federal Reserve economist John Fernald and Stanford University economist Charles Jones. They cite South Korea and China as examples of countries showing more rapid growth in research spending than the US, Europe, and Japan (Fernald and Jones 2014). Some 40 years ago China produced very few PhD’s in science and engineering; by 2010 China was producing a quarter more PhD’s than the United States. The fact that China and India represent more than one-third of the world’s population prompted Fernald and Jones to pose a question: “How many future Thomas Edisons and Steve Jobses are there in China and India, waiting to realise their potential?”

As the “Great Divergence” was set to commence, Adam Smith wrote in *The Wealth of Nations* that China “has been long one of the richest, that is, one of the most fertile, best cultivated, most industrious, and most populous countries in the world. It seems, however, to have been long stationary.” What was true in 1776 when Smith published his book and for two more centuries is no longer true. “In the United States and in the West, you have a certain way,” Jun Wang of BGI (formerly Beijing Genomics Institute) told Michael Specter for Specter’s story “The Gene Factory” about the Shenzhen-based genome sequencing giant’s bid “to crack hunger, illness, evolution – and the genetics of human intelligence” among other goals. “For the last five hundred years, you have been leading the way with innovation,” said Wang, BGI’s chief executive. “We are no longer interested in following”
Indeed, the center of gravity for technology investment may well be in the middle of the Pacific Ocean, the midpoint between the China’s bustling east coast cities with their numerous technology firms and the American west coast with technology hubs running from Seattle to San Diego (Oakley 2015).

**Innovation and Convergence in the Genomic Exchange Era**

Five hundred years ago, with China slipping from its earlier scientific pre-eminence, the rapid rise of global trade spurred by the spice trade, species exchange, and the introduction of novel food crops and biological materials and fibers was a boon to both urban development and capitalism in Europe. The Columbian Exchange linked continental ecosystems together, facilitating the global dispersion of plants including crop plants, animals, insects, invertebrates, allergens, and infectious microbes between the Old World and the New World (Crosby 1973). It launched what some biologists consider the beginning of a new biological era: the Homogenocene arising from the homogenising of ecosystems and loss of biodiversity (Samways 1999). The introduction of the potato to Europe from Peru may have accounted for a quarter of the growth in European population and urbanisation in the eighteenth and nineteenth centuries (Nunn and Qian 2011), easing ecological and population pressures and contributing to the incomes and productivity surge in the West.

Today spices like cardamom, cassia, cinnamon, ginger, nutmeg, pepper, and turmeric that spurred global trade in the European “Age of Discovery” are being intensively studied, particularly in India, for genomic markers to assist plant-breeding programmes (IISR 2011). The genomes of key crop plants in the Columbian Exchange have been fully or nearly sequenced. They include apple, banana, barley, bell pepper, cacao (chocolate), carrot, cassava (manioc), chili pepper, cotton, grape, maize, orange, papaya, peanut, pineapple, potato, pumpkin, rice, rubber, sorghum, soybean, squash, sugar beet, sugarcane, tomato, and wheat (Hoffman and Furcht 2014; Hoffman 2014). So have many domesticated animals in the exchange, including cat, chicken, cow, dog, goat, guinea pig, horse, pig, sheep, and turkey. The genomes of pathogens responsible for cholera, malaria, measles, smallpox, typhus, yellow fever, and other infectious diseases that devastated New World populations in the post-Columbian period have also been sequenced.
(Hoffman and Furcht 2014; Hoffman 2014). Meanwhile, hundreds of thousands of human beings of various ethnic stripes, infants included, have been decoded over the past decade (Regalado 2014), with the number expected to increase exponentially as sequencing technologies grow in productivity and decline in price (Wetterstrand 2015).

In our Genomic Exchange era, animal, plant, and microbial as well as human genetic and regulatory sequences travel around the world over high-speed data networks. Genomic sequence information about crop plants, livestock, natural materials and fibers, and pathogens is of great value for agricultural productivity, bio-based materials manufacturing, industrial bioprocessing, and biodiversity conservation as well as for disease diagnosis, treatment and prevention. Innovators can access such information from public sequence repositories like the National Institute of Health’s (NIH) GenBank, which holds DNA and RNA sequences from hundreds of thousands of species. China’s National Genebank in Shenzhen, which BGI established and operates, aims to become a comprehensive collection, banking, and sharing resource of biological specimens and bioinformatics data from humans, animals, plants, and microorganisms. BGI is also a leading participant in the Earth Microbiome Project, a multidisciplinary effort to determine the functional and evolutionary diversity of microbial communities across the globe and to produce a global Gene Atlas.

The Genomic Exchange era has the potential for creating new bioindustries based on the knowledge of life code and how the code builds and maintains proteins, cells, and organisms. The practice of technological innovation in the industrial era – the systematic application of ideas, inventions and technology to markets, trade, and social systems – is now being joined with the code of life, DNA, and the basic unit of life, the cell. Data systems are ramping up to handle the expected ‘big data’ deluge from whole genome sequencing and the promise it holds for precise, individualised medicine, personal health self-monitoring devices and apps, and next-generation drug development. The American technology entrepreneur and academician Vivek Wadhwa who studies how education, immigration, and entrepreneurship drive innovation makes a poignant observation: technologies involving Micro-Electro Mechnical System (MEMS) sensor-driven mobile health devices, nanobiology-based diagnostic platforms, 3D bioprinting, genomics, and DNA sequencing and synthesis
are advancing at exponential rates “even as their prices fall and footprints shrink” (Wadhwa 2015).

Innovation is poised to improve efficiencies, lower costs, and spur entrepreneurial activity in the $10 trillion global healthcare industry. In some cases, the developing countries can innovate faster than developed countries, the so-called leapfrog effect, because their governments are actively working to reform their health systems and they face lower regulatory hurdles (PwC 2015). Open innovation will serve as an entrepreneurial accelerator in these efforts because the diffusion of knowledge, the “public good par excellence” in the words of economist Thomas Piketty, is the greatest force for technological convergence among nations. The Genomic Exchange era will feature the inter-organisational sharing of anonymised genetic and biological data, the electronic linking of genotypic and phenotypic information in medical records, and device-driven patient empowerment and public health. With their promise of superior diagnostics, targeted therapies, and disease prevention, whole genome sequencing and whole exome sequencing are beginning to transform health care systems, a growing number of which are building sequencing capabilities in-house or partnering with industry.

In the West, Britain is proceeding to sequence 100,000 genomes through its National Health Service in partnership with Genomics England. The Obama administration in the US launched a precision medicine initiative in 2015 aimed at decoding the DNA of one million volunteers. The genomics entrepreneur J. Craig Venter and his new company Human Longevity, Inc. aim to sequence one million genomes by 2020 (Boulton 2015). In the East, BGI announced plans for a “Three Million Genomes Project” consisting of one million people, one million microorganisms, and one million plants and animals (Hardisty et al. 2013). On a much smaller scale, Singapore is performing deep whole genome sequencing of one hundred healthy Malays, an Austronesian group that is not represented in the 1000 Genomes catalogue of human genetic variation (Wong et al. 2013). Singaporean and British researchers have conducted whole genome sequencing or whole exome sequencing of several hundred South Asians in search of genetic variants underlying susceptibility to disorders such as type-2 diabetes and cardiovascular disease, which are prevalent in India and constitute a growing burden on its health care infrastructure (Wong et al. 2014; Chambers et al. 2014).
As technical barriers to human DNA sequencing decrease, as sequencing accuracy and depth grows, and as the cost of whole-genome sequencing approaches $1000, whole genome and whole exome sequencing will be used extensively in clinical medicine. Both can aid clinical diagnosis, reveal the genetic basis of rare familial diseases, and inform disease biology and drug response (Dewey et al. 2014). These technologies are also expected to uncover genetic findings of potential clinical importance in healthy individuals including infants. Perhaps more than any other sequencing service, BGI is positioning itself to be out front when genome sequencing takes hold in the clinic. Its sequencing horsepower, housed in a former shoe factory in the once sleepy fishing village of Shenzhen, has drawn the notice of multinational pharmaceutical firms with which BGI has a growing number of collaborations. One is the Asian Cancer Research Group (ACRG), jointly established by Lilly, Merck, and Pfizer. ACRG’s goal is to build a knowledge bank of cancers common in Asia by generating comprehensive open-source genomic data sets to accelerate drug discovery.

BGI chief executive Jun Wang revealed in early 2015 that his sequencing powerhouse is planning to gather and bank genomic, transcriptomic, epigenomic, metabolomic and microbiomic data from one million people, an unprecedented Million Omics Database Project (Heger 2015). The scientific pre-eminence China once possessed, chronicled by the historian, biochemist, and embryologist Joseph Needham in his seven-volume *Science and Civilization in China*, has not been forgotten in the Middle Kingdom.

**Biomolecules, Brainpower, and the Shifting Currents of Innovation**

Commercial use of tools from the revolution in molecular biology contributed more than $350 billion to the US economy in 2012 by one estimate, with a 10 to 15 per cent annual growth rate (Carlson 2014). If the US experience is a guide for future growth in the field world wide, each commercial sector of the biosciences – industrial biotechnology (including bioenergy), genetically modified plant crops, and biological drugs – will contribute roughly a third to overall output. Products arising from molecular biology constitute a growing share of the global economy with each passing year as technologies evolve, production processes improve, and markets expand. In recent years industrial biotechnology has been the
fastest growing biotechnology sector (Carlson 2014). That bodes well for mitigation of greenhouse gas emissions because bio-based products in the materials and chemicals sectors (as well as next-generation biofuels) have a much smaller environmental footprint than products such as petroleum-based plastics and petro-chemicals (OECD 2011).

Global investment in biotechnology has enjoyed solid growth since 2012, and 2014 was a banner year. *BioCentury*’s Walter Yang compared 2014 to 2013 (Yang 2015):

- Biotechnology stock indices advanced at an average of 31 per cent.
- The industry raised nearly $55 billion globally, up by 47 per cent.
- 112 initial public offerings (IPOs) raised a record total of $9 billion, up from 60 IPOs that raised nearly $4 billion.
- The number of IPOs in Asia-Pacific was 74 compared to 42; these IPOs raised $691 million over $309 million.
- The private sector raised a record $9 billion, doubling the amount from 2013. Asia-Pacific accounted for $274 million of private sector investment, up by 20 per cent.

Because of high drug development costs, estimated to average $2.5 billion for an approved prescription drug in the US (Mullard 2014), global investment in the biotechnology field remains highly concentrated in the biopharmaceutical sector. The biopharmaceutical industry, estimated to be a $150 - $200 billion global market, was founded on advances in molecular biology in the 1970s. Newer biological technologies like genomics, synthetic biology, and regenerative medicine are positioned where molecular biology was four decades ago, in the early stages of attracting significant investment (Woodford 2015). Some of these technologies are geo-technologies involving automated bioanalytical and biosynthesis instruments, systems, and devices often linked to data networks.

The biosciences have many new cutting-edge tools from genomics and bioinformatics, cellular technologies including stem cells, and synthetic biology, with assists from nanotechnology and automation. These tools make it possible to sequence and synthesize DNA at an industrial scale, edit genes precisely, control the growth and differentiation of cells and print them in three-dimensional constructs (bioprinting). They also make
it possible to create microbial factories that produce medicines, renewable fuels and chemicals, and biodegradable materials.

As noted above, growth in the industrial biotechnology sector – for cleaner and greener technology, chemicals, materials, and fuels – is vital for severing the link between economic growth and CO₂ emissions (OECD 2011; BIO 2013). We are at the dawn of the industrial enzymes era that is putting existing enzymes to novel uses and creating novel enzymes to catalyse an expanding array of biochemical reactions. Asia accounts for more than one-third of the multi-billion dollar industrial enzymes export market, with China accounting for 20 per cent (Binod et al. 2013). The potential for synthetic biology and metabolic engineering to accelerate growth in the design and manufacture of industrial enzymes and bio-based products is just beginning to be realised.

Genetic networks and biosynthetic pathways in microorganisms are being adapted, reorganised and recreated to manufacture biopolymers, bioacrylics, butanol, bio-isoprene for tires, surfactants, and 1,3-propanediol (PDO), a production platform for solvents, adhesives, resins, detergents, and cosmetics. The integration of software and wetware in synthetic biology (synbio) should dramatically shorten the innovation cycle for making new bio-based products (OECD 2014). Bioremediation has been employing microorganisms to reduce heavy metal contaminants in soil and water for several decades but with less than optimal utility. Synbio coupled with genomics, biosensing and ecosystem profiling constitute potentially invaluable tools for designing novel and much more effective environmental remediation systems for soil and water contamination, a significant problem for fast-growing countries in East and South Asia (Wong 2013; Banerjee and Sanyal 2011).

Genomics is opening a window on genetic alleles that enable food crops including wheat, rice, and maize (corn), Earth’s major cereal crops, to adapt to a changing climate. Their yield needs to grow by an estimated 70 per cent by mid-century to feed the projected nine billion people expected to then inhabit Earth (Kole 2013). Much of the overall population increase between now and 2050 is projected to take place in high-fertility countries, mainly in Africa but also countries with large populations such as India, Indonesia, Pakistan, the Philippines and the United States (UN 2013). The
challenge of feeding nine billion people without further deforestation and environmental degradation has resurrected the specter of Malthusian limits. As *The Economist* concluded in a special report, “The 9-billion people question” in 2011, feeding the world in 2050 given the ecological constraints on land and climate change “of which agriculture is both cause and victim” will be hard. Business as usual will not do it (Parker 2011).

Some of the production benefits of agricultural biotechnology have been achieved for large seed market crops such as maize, soybean, and cotton but not for the vast majority of food crops owing to regulatory hurdles, public apprehension, and political activism (DeFrancesco 2013; Camacho et al. 2014). Yet even with the powerful tools of food crop bioscience – marker-assisted selection, targeted mutation-selection, genetic modification, and others – it is not clear that current crops can be pushed to produce as well as they do now at expected higher temperatures and with less water. Researchers studying yield trends of four key crops from 1961 to 2008 found that more than a quarter of maize, rice, wheat, and soybean cropland areas worldwide are stagnating or in production decline (Ray et al. 2012), a clear sign that yield trends are woefully insufficient to double crop production by 2050 (Ray et al. 2013).

The molecular biology toolbox is filled with the contributions of microbes, but perhaps no microbially derived tools are as potentially game-changing as the new engineered nucleases. These nucleases can be directed to make double-strand DNA breaks at specific recognition sites of the genome. The genome editing technologies – zinc finger nucleases (ZFN), transcription activator-like effector nucleases (TALENs), and the CRISPR-Cas nuclease system – give scientists the unprecedented power to remove or insert specific DNA sequences, in principle anywhere in the genome and through an efficient and reliable process. Words, sentences, paragraphs, indeed entire pages of the book of life can be rewritten or entirely removed. Precise genomic editing has been demonstrated in a number of crop plants including rice, wheat, and sorghum. “This technology promises to change the pace and course of agricultural research,” wrote Jennifer Doudna and Emmanuelle Charpentier, inventors of the CRISPR-Cas9 genome editing system (Doudna and Charpentier 2014). Experiments show that precise genetic edits are passed to the succeeding generation of plants without new mutations or off-target editing, leading Doudna and Charpentier to conclude
that such findings “suggest that modification of plant genomes to provide protection from disease and resistance to pests may be much easier than has been the case with other technologies.” Synbio techniques for making multiple deletions, additions, and other edits to plant genomes stand out as a particularly important set of enabling technologies for instituting nitrogen fixation capability, improving nutrient content, and potentially enhancing photosynthetic efficiency (Lau et al. 2014; Rogers and Oldroyd 2014). The nearly 200 million tonnes of the nutrient fertilisers (nitrogen, phosphorous, and potash) used annually (113 million tonnes of nitrogen fertiliser) to meet the nutritional needs of the human population, particularly in East and South Asia, harm aquatic ecosystems, distort nature’s biogeochemical cycles, and contribute to climate change.¹² The tools for fixing nitrogen in cereal crops through expression of a functional nitrogenase enzyme in cereal plants or through transferring to these plants the capability to form a symbiotic association with nitrogen-fixing bacteria appear to be on hand.

**Conclusion: Brussels and Beijing: A Tale of Two Cities in an Anxious Age**

Government decisions in two cities separated by a third of the earth’s circumference help to illuminate the circuitous path ahead for bioscience, innovation, and ecosystems ecology. In late 2014, European Union political leaders in Brussels backed a plan to allow member nations to ban genetically modified (GM) crops on their soil even if the European Union approves them. In early 2015 the elected members of the European Parliament in Strasbourg, France voted by an overwhelming majority to allow member states to ban GM crops. They did so, *Nature Biotechnology* editorialised, “in the face of potential fines from the European Court and litigation from seed companies frustrated by foot-dragging and deadlock in European product authorizations” (NBT 2015). The ostensible justification for leaving the GM approval question with member states is subsidiarity, the principle that political decisions should be made at a local level if possible rather than made by a central authority. Since seeds and pollen do not recognise national borders, however, policymaking in high places and reality on the ground are likely to go their separate ways, resulting in genetic outcrossings and admixtures.
In leaving the decision to member states the European Parliament freed GM technology from “intense anti-GM lobbying at the heart of Europe” but may have paved the way for lengthy legal battles as each member country wrestles with the question of whether to move forward on GM crop approvals or ban GM crops entirely. Meanwhile, GM products approved by the European Food and Safety Authority, the EU regulatory body, are in limbo (NBT 2015). Only one GM crop – maize – is grown in Europe, mainly in Spain and Portugal (Lewis 2014). The “Frankenfood” movement has outpaced evidence-based rational analysis; culture has trumped science and entrepreneurship. On the question of GM crops, Western Europe, the innovative party in Pomeranz’s “Great Divergence,” is taking a distinctly different course from the one that changed the world two centuries ago.

As Brussels dithered and eventually punted, across the Eurasian landmass, in Beijing, the Chinese government exercised its central authority. It pledged more support for research on GM techniques, especially for crops. “After years of uncertainty, funding cuts and public arguments,” wrote ecologist Qiang Wang of the Chinese Academy of Sciences in Nature, “the country’s central government has issued a clear edict: China needs GM, and it will work to become a world leader in the development and application of the technology” (Wang 2014).

China sees the writing on the wall. Record Chinese imports of grain reflect dependency on others for the country to feed itself, an uncomfortable dependency illustrated by alleged Chinese theft of high-tech Western seed (Bunge 2015). To be self-sufficient, Wang observes, China must grow food for nearly one-fifth of the world’s population with just 6 per cent of the world’s fresh water and 7 per cent of the world’s arable land. The near doubling of grain production in China between 1978 and 2013 was driven by a six-fold rise in the use of chemical fertilisers. China may be the global factory, but it is agriculture, not industry, that is the main source of the country’s pollution. “GM technology has the potential to produce more food with less pollution,” Wang says.

The Chinese government awarded key patents to Davis, California-based Arcadia Biosciences for its transgenic nitrogen-use efficiency technology, which has shown improved productivity of rice and wheat along with decreased fertiliser requirements in field trials (James 2013).
Arcadia Biosciences’ GM rice has also produced strong yields under drought stress, based on field trials in India (Anderson 2015). China is expected to experience more frequent and more severe droughts with global warming. “The area of crops impacted and affected by droughts throughout the country has been increasing for several decades,” say Chinese climate scientists. “Since the beginning of the 21st century, regional droughts happened more frequently wreaking major havoc” (Ge et al. 2014).

China imports substantial quantities of GM maize (corn) and soybeans but grows only GM cotton, papaya and popular trees that serve as windbreaks in the windy north. Following a speech by Chinese president Xi Jinping that backed China’s development of genetically modified crops as a means of strengthening food security, agriculture minister Han Changbin followed up with measures for promoting GM food to the public (Hornby 2014). Beijing is counting on Chinese scientists, most of whom directly or indirectly work for the government, to educate a skeptical public about the benefits of GM technology (Wang 2015). More than 13,000 Chinese scientists work in agbiotech, China’s fastest growing biotech sector with $4 billion in annual government funding (Huang et al. 2012). The government’s investment in agbiotech R&D is designed to “raise agricultural productivity and ensure national food security through novel GM technology.” David Talbot in his article “China’s GMO Stockpile” captures the spirit of China’s determined effort:

Exuberant and prone to charming bursts of laughter, Caixia Gao embodies the optimistic, energetic present of GMO research in China. Wearing a gray T-shirt emblazoned with ‘Just Do It’ in large pink letters, she leads a tour of her greenhouses at the State Key Lab of Plant Cell and Chromosome Engineering at the Institute of Genetics and Developmental Biology, part of the Chinese Academy of Sciences in Beijing. She’s one of the world’s leaders in using sophisticated gene-editing technologies, including those known as TALENs and CRISPR (Talbot 2014).

China was the first world civilisation to create a non-patrimonial, modern state, which it did nearly two millennia before the modern state made its debut in Europe (Fukuyama 2014). The Chinese have far more historical experience than any other people co-existing with centralised administration and bureaucracy. Beijing has been very successful in planning and developing large, technically demanding infrastructure projects, which are typically accomplished with public acquiescence if not public
approval. Unlike most Chinese, Europeans are prepared to question science and scientists because of the power they can wield. “This could reflect the instinctive uneasiness that the average European would have with the concentration of power in few hands, something that the average Chinese might perhaps be less worried about” (Rerimassie et al. 2015).

China has cast its lot with evidence-based agricultural bioscience at a time of rapid growth in the country’s research and development and patent filings and when it is poised to become the world’s largest economy (if it isn’t already).13 Beijing’s decision to embrace GM crop production plus the extraordinary tools now available to reengineer plant genomes set against the Western Europe’s generally hostile view of the technology makes Pomeranz’s “Great Divergence” appear slightly shopworn. The new “Great Divergence” may be the gulf between rapidly advancing science and public opinion. More than any other science – Big Bang physics, climate change, evolution, vaccine safety – the American public is doubtful about GM foods and whether they are safe despite nearly three decades of testing.14 In a Pew Research poll, 37 per cent of American adults versus 88 per cent of American scientists surveyed considered GM foods generally safe to eat, a 51 point gap (Pew Research Center 2015).

China may not have had easily accessible coalfields or colonial resources as Britain possessed to fuel its industrial revolution, but today’s ecological and natural resource limitations and Malthusian pressures are coming into play in China and indeed throughout East and South Asia. When coal, steam, and mechanisation opened up vast new technical possibilities, “western Europeans (especially in England) were in a unique position to capitalise on them,” Pomeranz wrote in The Great Divergence. “Vast untapped New World resources (and underground resources) still lay before them, essentially abolishing the land constraint.” Once again vast new technical possibilities are opening up. Once again land is constrained. Dealing successfully with these possibilities and constraints in light of public misgivings about science would constitute a momentous achievement for twenty-first century political economy.
Endnotes


2 Pomeranz borrows the term “biological old regime” from Fernand Braudel (1992). Braudel’s chapter subtitle is: 1400-1800: A Long-lasting Biological Ancien Régime. He writes: “These then are the facts that go to make up the biological ancien régime we are discussing: the number of deaths roughly equivalent to the number of births; very high infant mortality, famine; chronic under-nourishment; and formidable epidemics.”

3 Dabla-Norris et al. (2013) at the International Monetary Fund note that the overall picture of growth among developing economies since the 1990s “masks an uneven pace of convergence across regions and countries, reflecting considerable heterogeneity in growth drivers.” In developing Asia, they write, rapid growth predated the 1990s, “with capital deepening playing a more important role in the catch-up processes of the faster-growing countries compared with other regions, fostered, in part, by high domestic savings rates in East Asia….”

4 For two centuries following publication of Adam Smith’s The Wealth of Nations, land, labour, and capital were the compelling and unchallenged inputs that economists took into account in their calculations for predicting economic output. Not until the second half of the twentieth century did that tried-and-true construct begin to give way when Massachusetts Institute of Technology economist and Nobel Laureate Robert Solow introduced the idea of technological progress as an additional factor in economic output, the “Solow residual.”


6 GenBank.gov
7 Nationalgenebank.org
8 Earthmicrobiome.org
9 For background information about Joseph Needham and his Science and Civilization in China series visit the website of the Needham Research Institute: http://www.nri.org.uk/.

10 Biopharmaceutical drugs or biologics now constitute approximately 20 per cent of the global pharmaceutical market with an annual growth rate of 8 per cent, double that of conventional pharmaceuticals. See Otto, Santagostino and Schrader (2014). India aspires to be a leader in the emerging biosimilars industry as it is in the generic drug industry. See Ail (2014).

11 See a world map of high-throughput sequencers at Omicsmaps.com.

12 For the amount of fertiliser nutrients (nitrogen, phosphorous, and potash) used annually, see FAO report World Fertilizer Trends and Outlook to 2018. The FAO writes: “The dependence of East Asia on nitrogen imports is expected to continue.” For a general discussion of the next steps to engineer crop plants that fix nitrogen, see Beatty and Good (2011). For the effects of nitrogen-based fertiliser on the nitrogen cycle, see Fields (2004) and Ward (2012). For a discussion on the impact of nitrogen fertiliser use on the environment and climate, see Foley et al. (2011).

13 Comparative data showing national research and development as a percentage of GDP is available in Chapter 4: “Research and Development: National Trends and International Comparisons” in Science and Engineering Indicators 2014, National Science Foundation, Washington, DC. Available at: http://www.nsf.gov/statistics/seind14/index.cfm/chapter-4/c4h.htm Among the highlights: “The pace of real growth over the past 10 years in China’s overall R&D remains exceptionally high at about 18% annually, adjusted for inflation.”

For a history of GM crop and food development, see Chapter 1 in Newton (2014). A scientific literature analysis of 700 papers on the subject of GM crops food/feed safety issues published between 2002 and 2012 show that “GM crops have been extensively evaluated for potential risks and that genetic modification technologies based on recombinant DNA do not carry a greater risk than other types of genetic modification.” (Sanchez 2015).

References


Divergence, Convergence, and Innovation: East-West Bioscience in an Anxious Age


Intellectual Property Protection in Bioinformatics and Open Bio Development

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Abstract: Bioinformatics has emerged as a new discipline to manage biological information by applying information technology tools so that useful results could be produced. Bioinformatics databases and software contain information bearing great potential for medical research. As a new emerging field, bioinformatics needs intellectual property (IP) protection to attract investors and promote innovation. Bioinformatics pose unprecedented challenge before the existing IP regime as the subject matters covered under it differ significantly from traditional subject matters of IP and sometimes they fall under the exclusions. Given the multifarious nature of bioinformatics, it is often difficult to suggest the best form of intellectual property protection to it. Technologies used in bioinformatics are interdependent and can be used as platform technologies and research tools by potential researchers. Aggressive assertion of IP over platform technologies and basic research tools may retard the innovation in bioinformatics. Open Bio development offers a solution in this regard that promotes open and collaborative efforts. However, IP advocates see Open Bio development as antagonistic to IP because it may reduce the incentives for innovators and creators and bring resentment among investors. Against this backdrop, the present article discusses the intricacies in providing effective IP protection to bioinformatics and critically analyse the interaction between IP protection to bioinformatics and Open Bio development.

Keywords: bioinformatics databases, bioinformatics software, patents, copyright, Open Bio development.

Introduction
Bioinformatics as a new discipline emerged after the rapid advancements in molecular biology and genetics. The new advancements such as genomics and proteomics along with the success of Human Genome Project unleashed great amount of biological information, promising great potential.
for medical research. The need to make the information useful through analysis and management of data led to the development of bioinformatics. Bioinformatics provide tools to catalogue analyse and manage the said information through tools like algorithms, databases and software. Since the information is basic to all types of biological research, the accessibility of the technologies used in bioinformatics become essential for the proper development of this discipline. However, the investors and developers of this field need certain reward, which encourages them to innovate and invest. Intellectual Property Rights (IPRs) have been seen as a viable model of protection in this regard, which ensure economic incentives for the investors, creators and inventors. Given the complex nature of bioinformatics; it is difficult to choose appropriate form of IP protection as patents, copyrights, trade secrets, etc., all have certain limitations. However, as a matter of practice, aggressive assertion of IPR over bioinformatics products is going on, given its potential to generate commercial results.

Critics allege that the extension of IP protection to bioinformatics is in conflict with its open and collaborative nature. How to devise certain mechanism, which ensures both the economic incentives for investors as well as promotion of open and collaborative efforts? This is a complex question before the lawyers, academics and policymakers, which can only be answered by an in-depth analysis of the open biotechnology-IPR interface. Against this backdrop, the present article discusses the complexities involved in providing the effective IP protection to bioinformatics and the conflict between IP protection to bioinformatics and open and collaborative biotechnology. The discussion is confined to two essential components of bioinformatics: bioinformatics databases and software.

**Nature, Definition and Scope of Bioinformatics**
The actual use of most of the information unleashed by the completion of human genome project and advancements in biotechnology was not fully known but the information was needed to be preserved for future use. The need to manage and catalogue the data containing information brought computer technology and biotechnology very close. The sequencing of gene and protein required comparison and analysis so that the disease can be identified and established. This task could not be completed manually and there was a great need of computers to perform this work in an efficient
manner. In the absence of computers, “a researcher could never view a single complete sequence, much less analyse it for patterns or anomalies, compare one person’s genome to that of another, or compare it to genomes of other organisms” (Gaff and Loren 2013; 15). Thus, the application of computers became essential for biology discipline. At the initial stage, however, the role of computers in the biotechnology field was restricted to the extent of data management and cataloguing. Gradually, the need to access information from databases and analyse them through software led to the emergence of a new discipline known as “bioinformatics”, which depicts a synergy between life sciences and computer technology. Bioinformatics has transformed lab-based biotechnology into computer-based science, which includes activities such as automated collection, compilation, storage, retrieval and analysis of biological data (Hultquist et al. 2003).

Given its versatile and complex nature, it is difficult to define the term bioinformatics. It has some overlapping with the term computational biology and both the terms are often used interchangeably. There is, however, significant difference between the two, as “computational biology sometimes connotes the development of algorithms, mathematical models, and methods for statistical inference, while bioinformatics is more associated with the development of software tools, databases, and visualisation methods.”¹ The National Centre for Biotechnology Information defines it as ‘a field of study in which biology, information technology and computer science merge together to form a single discipline.’² It is also defined as a discipline that includes “the collection, classification, storage, and analysis of biochemical and biological information using computers especially as applied to molecular genetics and genomics.”³ To put it broadly and simply, the term refers to “the use of the information technology in the analysis and organisation of data relating to biology” (Gaff and Loren 2013; 15). It involves technology, which mainly comprises computer programmes and software, for retrieval, analysis and comparison of relevant data and computer databases.

Bioinformatics involves technologies that can be used to gather, store, analyse and integrate biological and genetic information that can be applied to gene-based drug discovery and development (Jagdish 2013). The science of bioinformatics is essential to the use of genomic information in understanding human diseases and in the identification of new molecular
targets for drug discovery (Jagdish 2013). For example, researchers can use bioinformatics tools ‘to identify similarity between one gene sequence for which the function is known and another gene sequence for which the function is being investigated’ (Gaff and Loren 2013:15-16). Bioinformatics holds great potential for education, personalised medicine and health care and has increasingly become a competitive business model (Gaff and Loren 2013). With the emergence of bioinformatics and development of genomic databases, an increasing number of companies have gained possession of extensive collections of sequence information and data organised in database formats. The potential commercial value of these data has inspired these companies to effectively protect and leverage them through intellectual property protection (Horward and Gabriel 2002).

**IP Protection in Bioinformatics**

The potential of bioinformatics to produce commercial results attracted investors to invest in this new field and recoup their investment through intellectual property protection. However, the extension of intellectual property protection to bioinformatics is objected on numerous counts: IP protection would act to enclose the ethically sensitive realm of human gene-related studies; human genomic science should be common and accessible to all and should not be restricted to few individuals; and since the underlying purpose behind the bioinformatics is to further medical treatment, therefore patent protection to this field would adversely affect the medical research and accessibility to medicine (Gopalan 2009). The IP advocates counter these arguments on numerous grounds: IP protection in bioinformatics is necessary for encouraging innovation; as a new discipline, bioinformatics need investment, and investors can only be interested if there is an assurance as to recoup their investment; and IP protection ensures profits and generate considerable amount of funds to bring therapeutic products to the market (Marks and Steinberg 2002).

Given the complex nature of bioinformatics, it is difficult to offer best form of IP protection. The form of IP protection to bioinformatics depends upon the technology used such as algorithms, databases, software, etc. There is enormous confusion as to the viability of a particular form of the IP protection such as patent, copyrights and trade secrets in protecting bioinformatics databases or software as all forms of IP protection have
certain inherent limitations. For the purposes of this article, the discussion relating to IP protection in bioinformatics is limited to two major components: bioinformatics databases and bioinformatics software.

**IP Protection to Bioinformatics Databases**

Bioinformatics database represents an ‘organised body of persistent data, usually associated with computerised software designed to update, query, and retrieve components of the data stored in the system’ (Gopalan 2009; 48). The ultimate purpose of these databases is to provide easy access to information and facilitate retrieval of data for analysis and comparative studies (Gopalan 2009). Bioinformatics database is usually not a strong candidate for patent protection and majority of countries protect it through other forms of IP such as copyright and trade secret. As a mere composition of information, bioinformatics database is not eligible for patent protection but patent protection may be extended to it ‘if it is not a mere catalogue, but is more along the lines of data processing system that has the ability to convert the raw data into a tangible result’ (Gopalan 2009; 48). In the United States, through judicial construction, abstract ideas, natural phenomenon and product of nature have been excluded from patentable subject matter. However, the US Court of Appeal for Federal Circuit held that a data processing system is patentable subject matter as it involves the practical application of a mathematical algorithm, formula or calculation leading to a useful, concrete and tangible result. This interpretation may provide bioinformatics databases a scope for patent protection as they are not merely compilation of data but data processing systems (Gopalan 2009; 49). Such an interpretation is possible under Indian patent law that does not allow patents in mere presentation of information or computer programme *per se*. Here the term *per se* is open for interpretation to include bioinformatics database because “it is neither mere presentation of information nor a mere computer programme, but both combined with other operations which can be used in a number of applications” (Gopalan 2009; 49). There are certain inherent limitations of patent protection to bioinformatics databases: the patent application is required to be meticulously drafted to make the database an eligible candidate for patent; the scope of protection is confined only to the process of compiling and operating the database, viz. software or computer programme and does not extend to the data within the database;
it is a mere token protection and does not ensure total exclusivity of the data compiled (Gopalan 2009; 49).

Copyright seems to be the most efficacious mode of protection of the bioinformatics databases. It protects the form of expressions, which is original and creative. In the United States, copyright law is used to protect compilation of databases. It protects “expression” created by an “author,” but excludes from protection any “idea, procedure, process, system, method of operation, concept, principle, or discovery”. It reflects that copyright law does not offer any sort of protection to scientific discoveries or discovered facts and therefore, information in bioinformatics databases such as GenBank, Data Bank of Japan (DDBJ), and European Molecular Biology Laboratory (EMBL) databases as pure research results and sequence data, are not protectable (Howard and Gabriel 2002). In *Fiest Publications Inc v. Rural Telephone Service Co.*, [499 US 340], the US Supreme Court held that facts are not copyrightable but compilation of facts, provided that there is sufficient degree of originality in the compilation in terms of selection and, arrangement of terms, in terms of indices employed, etc. (Gopalan 2009; 49). For instance, if a compilation is derived from a process characterised as ‘thoughtful’ selection, protection can be afforded; however, selection or arrangement characterised as ‘obvious,’ ‘typical’ or ‘routine’ would remain unprotected (Howard and Gabriel 2002). Interpreting the term ‘originality’ in *Fiest Publications Inc v. Rural Telephone Service Co.* (499 US 340, 362), the US Supreme Court maintained that the term “does not require that facts be presented in an innovative or surprising way,” nevertheless, it prescribes that “the selection and arrangement of facts cannot be so mechanical or routine as to require no creativity whatsoever” (Howard and Gabriel 2002; 48).

Contextualising, this interpretation to the facts of the case, the Court held that telephone “white pages” employing an alphabetical organisation lack sufficient creativity because such organization “... is not only unoriginal, it is practically inevitable”. Similarly, organisation of database sequence information by functional categories or keywords such as “gene name,” “protein name,” “author names,” “organism names,” or other widely used and obviously functional categories may lack the requisite creativity for copyright (Howard and Gabriel 2002). Since copyright protection is limited to the form of expression. In order to establish copyright infringement through copying, the selection and arrangement of new work must be
substantially similar to the original work. As a result, the database owner is left with little recourse against rearrangement in non-infringing formats or against uses of individual pieces of information (Howard and Gabriel 2002).

In response to the difficulties in the form of originality and copying of copyright protection, the most dramatic provision is the European Union’s 1996 “Directive on the Legal Protection of Databases,” which applies copyright-type protection to certain compilations of data regardless of creative organisation (Howard and Gabriel 2002). The EU Database Directive confers a two-tier protection for databases: first, the copyright protection to databases; and second, the sui generis rights, which could be used to protect the maker’s investment on some special but non-original databases (Chang and Xuezhong 2010). Copyright protection for databases was available to countries and parties under the Berne Convention and TRIPS Agreement and the sui generis right was made available only to makers who are nationals of EU member states (or have their habitual residence in the community, or companies formed in accordance with the law of a member state and having their registered office, central administration or principal place or business within the community) (Chang and Xuezhong 2010). The EU Directive recognises that ‘a person who has made a substantial investment in obtaining, verifying or presenting the database must have right of exclusivity over it’ (Gopalan 2009; 49). Therefore, it protects the investor against unauthorised extraction of the information or utilisation of the whole or a substantial part of the database (Gopalan 2009). Some suggests contractual licenses and trade secret as viable methods to protect database contents from disclosure; however, publicly accessible databases can result from inadvertent or pirated disclosure (Howard and Gabriel 2002).

**IP Protection to Bioinformatics Software**

In most of the countries, bioinformatics software is usually protected through copyright rather than patents. However, patenting of software is also gaining importance with certain qualifications. The United States pioneered in providing patent protection to software. In the United States, patent law excludes from patentability abstract ideas, scientific laws, naturally occurring phenomena, products of nature, mental steps, and printed matter. However, cases such as *State Street Bank and Trust v Signature Financial Group, Inc.* [149 F.3d 1368 (1998)] and *ATT v Excel Communication*
Inc.[172 F.3d 1352 (1999] opened scope for patenting of bioinformatics software. It has been established by courts that in order to make software patentable, the data residing in the software must “interact” with a computer readable medium, i.e. they must be able to direct a computer to accomplish a particular result (Rees 2003). Due to involvement of computer-based applications such as database and software for the collection and processing of biological data, the United States Patent and Trademark Office (USPTO) defines this category as “inventions implemented in a computer-readable media”.8

In the compliance of the decisions made by the Court of Appeal for Federal Circuit (CAFC) in the cases, In re Warmerdam [31 USPQ 2d 1754 (Fed. Cir. 1994)] and In re Lowry [32 USPQ 2d 1031 (Fed. Cir. 1994)], the USPTO explained the reason for the statutory distinction between data structure per se and those encoded on a computer-readable medium or machine in the Guidelines:

Data structures that are not claimed as embodied in computer readable media are descriptive material per se and are not statutory because they are neither physical “things” or statutory processes. Such claimed data structures do not define any structural and functional inter-relationships between the data structure and to her claimed aspects of the invention which permit the data structure’s functionality to be realised. In contrast, a claimed computer-related medium encoded with a data structure defines structural and functional interrelationships between the data structure and the medium which permit the data structure’s functionality to be realised, and it is thus statutory.9

As of now, software is considered as patentable subject matter under the US law, if it produces a useful, concrete and tangible result. Likewise, bioinformatics software is also eligible for the same protection because such software can be used for the purpose of biological research to produce results which are tangible, concrete and useful (Gopalan 2009). The US Supreme Court’s 2010 decision in Bilski v. Kappos [561 US 593 (2010)] has broadened the test for what is patentable subject matter ‘by stepping back from the so called machine or transformation test, which could have limited the patentability of bioinformatics’ (Gaff and Loren 2013; 17).

Assuming that an invention is not excluded from patent protection, a practical challenge for the bioinformatics industry is that the examiner must review the application from the point of view of a person skilled in the art. Applicants must make their application so clear to avoid any indices
of abstract ideas to get the patent successfully. Patent office must guard against patent for abstract ideas by requiring applicants to disclose “specific, substantial and credible uses of claimed invention” (Gaff and Loren 2013; 17). In 2014, the USPTO published guidelines related to examination procedure for computer related inventions, which prescribe different steps to ensure that the invention must not fall under abstract idea and necessarily produce some tangible results and involve functionality.10

Patentability of software has been a problematic issue in Europe too. The European Patent Convention (EPC) excludes computer programmes from patentability. However, the European Patent Office (EPO) in Germany realised very soon that the foundation for exclusion was illogical (Hultquist et al. 2003). While giving broad interpretation to EU patent law in VICOM decision11, the EPO pointed out that the wording of the European Patent Convention excluded only the patenting of computer programmes as such (Hulquist et al. 2003). Nevertheless, a general-purpose computer programmed for a special purpose is not excluded from patentability as long as it produces a technical effect (Hulquist et al. 2003). The VICOM decision opened the gate for the patenting of inventions implemented by means of computers in Europe (Hulquist et al. 2003).

The Patent Act 1970 of India also excludes patent on computer programme per se (Section 3 (k) of the Patents Act, 2005); however, the term per se could be construed widely to include bioinformatics software. Therefore, a computer programme including bioinformatics software coupled with some hardware component may fall under the scope of patentable subject matter, ‘if the claim is cleverly constructed in such a manner that the patent appears to be for the hardware, but the protection is claimed for the software as well, as an integral component’ (Gopalan 2009; 50). The Guidelines for Examination of Computer-Related Invention 2013 published by the Office of the Controller General of Patents, Designs and Trademarks maintains the similar stand, which defines computer related invention as any invention which involves the use of computers, computer networks or other programmable apparatus and includes such inventions, one or more features of which are realised wholly or partially by means of a computer programme/programmes.12 Therefore, according to Indian Patent Office (IPO), ‘computer programme by itself is not patentable, but with a combination of hardware components
(hardware limitations like processor, memory, interfaces) a computer programme will prima facie be considered patentable.’ However, IPO places an additional requirement that hardware must be more than a general purpose computer, meaning thereby that novel features existing in the line of codes are not patentable (Dewan 2013).

Under the copyright laws, the term “literary work” has been construed to include software and protection accorded to it has been extended to human identifiable language, source code and machine readable component object code (Gopalan 2009). In the United States, computer programmes are protected as literary works under the definition in the Copyright Act (17 US C. § 101). Copyright for computer programmes prohibits not only literal copying, but also copying of “non-literal elements”, such as programme’s structure, sequence and organisation. However, there is limitation with non-literal aspects; these aspects can be protected only “to the extent that they incorporate authorship in programmer’s expression of original ideas, as distinguished from the ideas themselves”. In Europe computer programme is protected as literary work under the European Union Computer Programmes Directive 2009/24/EC. Indian copyright law extends copyright protection to software under the term literary work. Computer programme under the Indian Copyright Act 1957 has been defined to include both source code and object code (Section 2 (ffc) of the Copyright Act, 1957). Therefore, bioinformatics software can be protected as a computer programme under the Act as long as the work is an original expression of the idea of the person creating the programme (Gopalan 2009). Copyright protection is not the best form of protection for software as the protection extends to the original expression of the idea. It gives scope for others to merely change some aspects of the object and source code to claim an independent copyright (Gopalan 2009).

Trade secret has also been used to protect computer software as code writers maintain the source code of their programmes as a trade secret, releasing only the object code for sale or license. However, in the field of bioinformatics software, where there is a definite desire to market the product, there is possibility that the trade secret may be disclosed by reverse engineering, i.e. the object code may be used to reach the source code (Gopalan 2009). Through reverse engineering, customised bioinformatics
apparatus might be stripped down and each individual component analysed to understand the protected trade secret (Gopalan 2009).

**Bioinformatics and Open Bio Development**

Bioinformatics comprises databases and software that contain information which is fundamental for researchers to make it useful for medical and diagnostic purposes. The collaborative nature of bioinformatics demands openness and sharing of information among researchers, scientists and innovators. Taking this into consideration, the developers of Human Genome Project made it clear that data obtained from HGP-funded research must be publicly available. Such efforts are based on the fact that the knowledge and understanding of new disciplines such as human genetics and genomics can only be accelerated, when the researchers have access to the current information. However, the developers and fund givers of many other initiatives similar to HGP have a subsidiary goal of creating the technology for economic benefit. With this, the creation and upkeep of private genomic databases has begun.

IP protection is seen as a viable model to recoup the benefits of investment by the investors. As a new discipline, IP protection is advocated by the investors, inventors and creators in the field of biotechnology and bioinformatics. However, the aggressive assertion of IPR in this field may pose a threat to the openness and sharing of research results which is *sine qua non* for biotechnological innovation. The increased commercialisation of biotechnological research compelled members of the scientific community to think seriously about the impact of such databases on research ventures. This led to the Open Bio development, which is seen as a viable approach to ensure access to genetic information for researchers and scientists. Open Bio is destined to promote the continued open access in biotechnology. This movement has been inspired by the success of Free and Open Source Software (FOSS) movement (Issac and Park 2009).

**Open Development**

Open development involves a collective collaborative process, which ensures the free exchange of information relating to technology among researchers. Moreover, users of technology or research tools suggest new improvements in functionality or interface and they may rely on open
disclosure to encourage innovation. Open development promotes access to basic research tools so that innovation is encouraged in a particular field, but it may also pose risk of minimising the profit from commercial R&D in the area of research tools (Issac and Park 2009). The actual and overall impact on innovation depends on conflicting influences: “an open innovation process may lower the cost of research tool innovation by eliminating the transaction costs of license negotiations, but the potential benefits of inventive activity may no longer include possible profits from licensing the innovation” (Issac and Park 2009; 240).

Free and Open Development reflects a situation, where innovations are shared freely without any obstruction of IP claims and the distribution of modified technology may be regulated in a manner which ensures that the modification to the modification also remains free. Nevertheless, IP protection may be claimed and granted but the licensing to use, redistribute and modify the technology is provided gratis by the developer. This ensures that not only the enabled technology remain free and open but also the patented and copyrighted technology (Issac and Park 2009). FOSS is a great example of successful open development.

Open source software enables the end users with the ability to study, change, modify, and redistribute the software they use. There are two basic components of the software, which can be freely distributed and redistributed: object code and source code. Most of the software is distributed in the form of object code, a series of ones and zeroes that can be read by computers but in order to modify the software, a programmer needs the source code. Object code is written in the series of ones and zeros in a language that is comprehensible to computers but not comprehensible by human, even skilled programmers. On the other hand, source code, which is again a compilation of one and zeros found in the object code into a language that can be understood by persons skilled in the art of programming. The problem in making source code open and accessible led to software pioneers to develop a model in which source code is distributed along with object code, and users are authorised to distribute and modify the programme at their individual ends. This provides wider user community an option to review and adopt most successful modification (Feldman 2004).

Under free and open standard any party is licensed to read and implement it without payment. The best example of open standards body
of the internet is the World Wide Web Consortium (W3C) standards, which are focused on data exchange and display. The W3C standards are widely adopted and widespread, ensuring a remarkable level of inter-operability on the internet. No such system is in operation in the biotechnology field that plays a similar role as the W3C plays in the field of information technology. Nevertheless, significant efforts are being made to promote open standards, particularly in the areas of data exchange and inter-operability (Issac and Park 2009).

Open biotechnology is a multifarious term, which reflects various forms of open mechanisms in the field of biotechnology. It has been used to refer to such different projects as an open journal (e.g., Public Library of Science), a new bioinformatics tool (e.g., the BioMoby messaging standard), a database (e.g., NIH db GaP), a big science project (e.g., HapMap or the Human Genome Project), a project to facilitate access to biotech research tools (Cambia BiOS) or a combination of these (Joly 2010). Open Bio movement is focused on providing access of platform technologies and research tools to research community to promote innovation in biotechnology. This could be done by open licensing, pooling of technologies, research exemptions and other initiatives.

In the context of bioinformatics, open source analogy has been applied to biotechnology to harness the communication, licensing and organisational innovation. For example, BIOS Initiative is an attempt to extend the concepts of open source to biotech innovation (Issac and Park 2009). Though open source software movement enhances free and open sharing of source code and object code of software and makes innovation accessible to wide research community, however, it is plagued with some discrepancies. One of them is the challenge of ensuring that after the source code is released to the public, it remains available for future users to modify and distribute. In open source development, if developers renounce their copyrights on codes, leaving it in public domain, those who make improvements may enclose the improved version by asserting proprietary claims. This would degenerate the open source project and create a situation where the best versions of the programme might be proprietary, and the software could become closed (Feldman 2004).

Open development has made a dramatic impact on databases too. One of the best examples of open and collaborative database is the International Intellectual Property Protection in Bioinformatics and Open Bio Development
Haplotype Mapping (HAP MAP) project. There is a significant difference between software and databases to the investment. As compared to the former, generation of the latter can require substantial capital investment (Rai 2005). This necessitates that despite making data generation open and collaborative, some sort of restriction on participation as well as public funding should be imposed. Given the high cost required for database generation and dependency on public funding, it is unlikely that private database businesses can be built on a service model (Rai 2005).

**Different Models of Open Bio Initiatives**

Open source development inspired the researchers, scientists, public and private organisations to take open bio initiatives, which facilitate the continued access and sharing of research tools and research results. In the due course of time, various open bio models came into existence, which functions differently but with a common objective to promote open access to technology (Feldman 2004).

1. **Human Genome Project**

Human Genome Project (HGP) was probably the first reflection of open bio initiative promoting access to genomic database through collaborative mechanism (Rai 2005). The producers of the human genome sequence made the genomic data public through an open source software programme, known as the distributed annotation system (DAS), aimed at facilitating collaborative improvement and annotation of the genome. The data dissemination and improvement policy of the HGP and other large scale genome mapping projects was carried on and developed by the National Institute of Health (NIH), which then imposed on the administrators of the participating universities. The commercial potential of genomic information through sequencing led to the private organisations to make private sequencing efforts and generate information for price. Such an effort was made by Craig Venter to keep private upkeep on genomic sequence databases developed by him. In order to check such private efforts, there were discussions within the HGP over using some type of “copy left” license on the data produced by the project. Copy left denotes “right to freely use, modify, copy, and share software works of art, etc., on the condition that these rights be granted to all subsequent users and owners.” Copy left license
was suggested with the view to prevent private entities, particularly Craig Venter from gaining advantage over the public data, by making proprietary any improvements Celera made to the public data. The HGP leaders rejected a copy left approach; however, it led to NHGRI along with other funding organisations to adopt a copy left style policy in setting up the International HapMap Project (Rai 2005).

2. HapMap Project
HapMap project is aimed at developing a map that describes the common patterns of human DNA variations. The project makes the information generated by it freely available with a condition that those who access the data do not restrict the access of others (Feldman 2005). The data access policy of the project maintains: “users agree not to reduce other’s access to the data and to share the data only with others who have made the same agreement” (Issac and Park 2009; 238). It allows the patent of subsequent discoveries “as long as patentees do not prevent others from obtaining access to the project’s data” (Issac and Park 2009; 238).

3. SNP Consortium
The Single Nucleotide Polymorphisms (SNP) Consortium is another example of open bio initiative, which facilitates the accessibility of research tools to advance industry goals (Issac and Park 2009). Under this Consortium, several large pharmaceutical and technology companies have joined hand with Welcome Trust and academic researchers to file patent applications on single nucleotide polymorphisms (SNPs) that will be freely accessible to all (Issac and Park 2009).

4. Public Patent Foundation
Public Patent Foundation projects work as a protected commons in which patent holders would agree to pool their technologies, which would subsequently be made available to all participants for free. These projects maintain a system of protected commons to tackle the problem of patent thickets, where presence of so many overlapping patents make it difficult for researchers and even those who hold patent themselves, to operate. Under these projects, in each commons, patent holders would grant non-exclusive licenses to a public trust that would then make all of the technologies available to the participants. Robin Feldman compares these functions
of commons with that of a disarmament treaty that permit only bilateral participation. This implies that one cannot benefit from the patent commons without placing one’s rights in the commons as well (Feldman 2004).

5. Biological Innovation and Open Society

Biological Innovation and Open Society (BIOS) is an initiative, which aims at assembling the groups of enabling technologies that together provide the pieces necessary for a particular form of research investigation. For instance, a BIOS group, or node, might contain a core technology, or groups of technologies, necessary for introducing new genes into plants. Such technologies need not to be superior to existing commercial technologies but sufficiently effective tool for engaging in the basic research so that there is no obstacle in the form of patents. The initiative recognises the interdependent nature of technologies involved in biotechnology field. This is why the founder of BIOS, Richard Jefferson compares this interdependence with wheel and spoke analogy, where biological technologies require several key components to function, just as a wheel requires a number of spokes in order to operate. Through BIOS, Jefferson hopes that it will be able to provide participants with complete packages including all the spokes (Feldman 2004). These technologies under BIOS are freely available to anyone with a condition that users will be required to sign a license agreeing to grant back any improvements in the core technology and to make such improvements freely available to all others on the same terms that BIOS provided for the original core technology. BIOS licence permits users to patent any invention created, which is not an improvement to the core research tool technologies (Feldman 2004).

Given the different nature of technologies involved, the application of open source analogy also differs in information technology and biotechnology. For instance, in information technology, most of the software is protectable through copyright; products of biotech are usually protected through the patent system (Joly 2010). Unlike Information Technology, the high cost and legal uncertainty attached with the patents make it difficult to develop open patent licensing system in biotechnology. This compels a patent holder, who grants open patent license to charge sufficient cost to its licensee to recuperate its investment in the patent. This raises question, whether the
patent system can be used in biotechnology in the same successful manner as copyright is used in information and technology to promote open and collaborative innovation. In information technology, free and open source software involves quality software, which is being produced as a hobby by amateurs, perhaps even by teenage hackers while biotechnology requires a team of scientists with advanced degrees, and the credentials of scientists and engineers matter. Once one moves outside the realm of bioinformatics, open source becomes a metaphor for open development that includes access and sharing of the underlying technological secrets or information and giving access.

**Is Open Bio Movement in Conflict with Intellectual Property?**

One of the underlying policies behind the patent is that it stimulates innovation and diffusion by raising the private return to research, development and commercialisation and if open development lowers this private return, growth may suffer (Issac and Park 2009).

In this context, Open Bio Development is seen as antagonistic to IP as it demands openness against the monopoly and leads to IPR infringements or misuses. For instance, it leads to patent misuse, which is defined as an impermissible attempt to expand the time and scope of the patent beyond the patent grant. Open Bio models include improvements in the core technology that may not be within the teachings of the original patent (Feldman 2004).

Since open source biotechnology licenses necessitate that advances in the technology must be made available to others on the same open terms as the original technology, the open source group may be using the power of the patent grant to reach an invention outside the original patent. The question arises whether this activity in the open source biotechnology licensing constitutes patent misuse. Answer could be found by analysing the overall impact of open biotechnology on innovation. Although open source biotechnology may decrease some downstream economic returns, it increases downstream non-economic rewards as open source licensing may increase the level of downstream innovation by encouraging the exploitation of certain types of untapped. Open source development effectively tackles the problem of patent thickets, which remove the short-term restriction of
supply that is expected under traditional patent licensing. The overall effect of the open source system is to increase the supply of innovation and the speed at which such innovation is available for the public benefit, effects that are consistent with patent policy (Feldman 2004).

The main purpose of the patent system is to promote the progress of science for the public benefit. Open source biotechnology accelerates the moment at which knowledge is widely available to the public, bringing inventions into the public domain for the public benefit. This seems to be consistent with the patent policy (Feldman 2004).

Yann Joly maintains that there is the possibility that an open biotechnology could also include a mechanism to allow the initial researchers to recuperate reasonable production costs invested in its realisation. He further suggests that a variety of licensing schemes with or without IP (e.g., patent pool, non-assertion covenants, public domain, protected commons agreement, contractual licenses) can theoretically be used as the engine to support the open nature of the project (Joly 2010). Therefore, open biotechnology is not antagonistic to IP and it is quite possible to develop an open source project that would make use of the patent system.

Developing countries see an opportunity in Open Bio development that enables to imitate, learn and innovate without violating their IP agreements. Here, Open Bio development significantly lowers the cost of entry into biotech research, opening gates for developing countries with limited resources (Issac and Park 2009). Maurer, Rai and Sali propose that open source software can provide a model for improving innovation in tropical medicine; since open source discoveries remain unpatented, the zero licensing fees and competitive pressures will conspire to keep prices low (Maurer et al. 2004). Developing countries may have increased free access to research data and research tools under Open Bio and this accessibility may reduce the pressure on these countries to transgress IPR standards. However, Open Bio on its own would not bring desired results unless and until it works as a complementary vehicle to targeted government research support (Issac and Park 2009).
Conclusion
IP protection in bioinformatics is a complex issue as it is difficult to suggest the most effective form of protection because each form, such as patent, copyright and trade secrets, has certain inherent limitations. Inventions and creations under the bioinformatics are posing altogether new challenges before the existing IP regime, which are the outcome of the present information age rather than industrial age. In this light, IP protection to bioinformatics requires a fresh approach which assimilates new realities of the present information age. Given the collaborative nature of bioinformatics and interdependence of technologies involved in it, the aggressive assertion of IP may have an adverse impact on innovation. The current practices suggest that due to commercial potential of bioinformatics, research in bioinformatics is increasingly proprietary and secretive, which creates fears that future progress may be impeded by restricted access and licensing difficulties. Open Bio and open source biotechnology development give hope against this problem. However, there is a possibility that these developments may reduce incentives for inventive and creative efforts made by inventors and creators. Bioinformatics as an emerging field needs IP protection to attract investment and to encourage inventors and creators. Any assessment of the impact of IP protection on Open Bio development would be extremely tentative as the field is still evolving and in transitional phase. Open development is gaining importance in several areas including operating systems, scripting languages and sequencing algorithms. Open source bioinformatics software and databases also illustrate possibilities for free and open development with the models that include IP mechanisms. How to develop licensing strategies and devise protective methods, that strikes a balance between IP protection and Open Bio development, and promoting innovations are the potential issues for researchers and policymakers.

Endnotes
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References


Obsolescence of First Generation GM Cotton Seed: Is It Planned?

Haribabu Ejnavarzala*

Abstract: Genetically modified cotton seed with a gene engineered from Bacillus thuringiensis (Bt) produces a toxin that kills Bollworm, a major pest that attacks cotton crop, and was introduced in Gujarat in India in 2002. The Government of India gave formal approval to Mahyco-Monsanto Biotech Limited, a joint venture company between Monsanto, which has patent rights over Bt technology and Mahyco, a leading Indian seed company for commercial release of Bt technology in cotton crop in 2002. Bt cotton cultivation spread to major cotton growing states such as Andhra Pradesh, Maharashtra, Punjab and Madhya Pradesh. Today in India 80 per cent of cotton cultivated is GM cotton. The first generation GM cotton seed, which had the Cry1Ac gene, has recently been shown by the company to be ineffective as it has not been able to fight the bollworm on the ground that the pest developed resistance against the toxin. Based on the company’s assessment of the performance of the first generation Bt cotton seed in 2009 in Gujarat, the company declared that the first generation Bt cotton seed has become ineffective as it could not fight pink bollworm. The company introduced the second generation Bt cotton seed into which an additional gene - Cry2Ab - in addition to Cry1Ac was engineered. The article raises the following questions: Could the company’s attempt to make the first generation Bt cottonseed prematurely obsolete be a deliberate corporate strategy to introduce a new seed with some incremental modification so that the company could extend its monopolistic control over technology? Did the company find the first generation GM cotton seed ineffective against the pest in all the states? Was there an independent assessment by the regulatory bodies to establish whether or not the first generation seed has lost its capacity to fight the Bollworm? In the capitalist mode of production planned obsolescence is a corporate strategy to increase the price of the product and charge new technology a higher license fee to maintain enhanced profit margins. With industrialisation of seed production the logic of corporate strategies in modern

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industrial sector is carried over to agriculture seed production as well. Planned obsolescence creates a situation in which agricultural technology becomes inaccessible and makes it difficult to achieve inclusive development in a country like India where the average size of land holdings in case of over 50 per cent of the farmers is less than five acres.

**Keywords:** Planned obsolescence monopoly, technology regulation, Bt Cotton, technology assessment

**Introduction**
Industrialisation of agriculture began with farmers using external inputs – chemical fertilisers, pesticides – manufactured by industry and hybrid seed, produced by seed industry – since the early part of the 20th century in the western countries. Entry of the capitalist enterprises in hybrid seed production marks the beginning of the industrialisation of seed production in the first half of the 20th century (Kloppernburg 1988). Prior to the development of hybrid seed, private industry could not enter the seed sector as farmers controlled selection and breeding of seed varieties and production and exchange of seed. Information about varieties was in the public domain. With the hybrids the information on the parental lines from which a hybrid was produced was guarded as a trade secret by the industry and this was protected by law in US as a breeder’s right (Kloppenburg 1988). It meant that the farmers could not save hybrid seed for the next season and exchange it with fellow farmers, because of the proprietary nature of hybrid seeds. Moreover, hybrid seed loses its vigour after repeated use. Hybrid seed production was based on phenotypic selection of parental lines to produce hybrids. In terms of time taken to produce a stable hybrid it took about seven to ten years.

Advances in molecular biology enabled scientists to understand life processes at molecular level and also intervene at molecular level. In the 1970s scientists discovered that discrete genetic material can be transferred from one organism to another. This enabled scientists to engineer genes from one organism to another not only within a taxonomic group but across taxonomic groups as well. For example, production of Bt cotton seed involves transfer of Bt toxin from Bacillus thuringiensis into cotton plant. In contrast to the production of hybrids based on phenotypic selection production of genetically modified seed is based on genotypic selection at molecular level. Further, it reduces the time required to produce the GM seed to about three years.
**Pest Resistance against Chemical Pesticide**

Conventional cotton hybrids were susceptible to pest attacks, the major pest being the Bollworm. Increasing use of chemical pesticide against Bollworm could not eliminate Bollworm. Overtime the pest developed resistance against pesticides. It is in this context that genetically modified cotton seed was developed. An insecticidal protein from Bacillus thuringiensis, a soil bacterium, was first successfully engineered into cotton seed in 1987. The protein, Cry1Ac, equips cotton plant to fight Bollworm. If the Bollworm feeds on Bt cotton plant the Bt toxin in the plant kills the pest, thus reducing the need for using pesticide. It is a bio-innovation in contrast to the earlier solution based on synthetic chemicals. Monsanto succeeded in producing the Bt cotton seed and established its proprietary control over the technology by obtaining a patent and consequently licensed its technology to seed companies in different countries. Recently, Monsanto developed the second generation Bollgard II which has two Bt proteins - Cry1Ac and Cry2Ab. This pyramiding of two makes it difficult for the pests to develop resistance against two proteins. However, proprietary control over Bt technology has implications for pest management strategies and corporate attitude towards development of new strategies of pest management and control. Laxminaryan and Fischer (2004) raise the following concern:

.....can we count on private sector to provide an adequate technological response to the pest problem? Consider the case of resistance to antibiotics. For many years, physicians freely used the available antibiotics in the belief that pharmaceutical companies would continue to develop new ones. However, the widespread resistance to existing antibiotics increases the probability that any new drug will be ineffective shortly after its introduction, and this cross-resistance makes the return on investment risky. Although this does not yet appear to be the case for Bt crops, it may not be an unlikely scenario in the future.

**Bt Cotton Seed in India**

Farmers of Gujarat were the first ones to use genetically modified seed even before the seed was approved by the regulatory agencies in 2002. The Government of India gave formal approval to Mahyco-Monsanto Biotech (MMB) Limited, a joint venture company between Monsanto, which has patent rights over Bt technology and Mahyco, in 2002 for commercial
release of Bt cotton. Monsanto Mahyco Biotech (MMB) Ltd. licensed the Bt technology to several Indian seed companies to incorporate Bt gene into their hybrids for a license fee. The use of Bt technology spread to all major cotton growing states in India and by 2011-2012 about 80 per cent of the total cotton area (23.5 million acres out of 29.6 million acres) was covered with Bt cotton hybrids.

Farmers who adopted Bt cotton in some states like Andhra Pradesh do seem to be satisfied with the performance of Bt technology as a crop protection technology in the sense it fights the major pest, that is, Bollworm without the application of chemical pesticide. Stone (2011) observed that in Warangal district of Andhra Pradesh the use of Bt cotton seed has contributed to increase in productivity by 18 per cent and decrease in pesticide use by 55 per cent, but there has been increase in pesticide use to tackle the secondary pests.

The yield increases are on account of reduction in yield losses due to pest attacks. However, in India variations have been noted in the performance of Bt cotton in different agro-climatic zones – rain-fed regions and irrigated areas, soil conditions – since its introduction. In a recent comparative study of Bt cotton performance among the US, Australia, China, India, and South Africa by Finger et al. (2011) concluded:

…the published effects of Bt cotton are very heterogeneous between the countries. This heterogeneity increases even more when going from the national to regional scale within a country. For instance, results for the effects of Bt cotton in India show a huge within-country heterogeneity ranging from negative effects to very promising increases of yields and gross margins.

**Signs of Pest Resistance against Bt Toxin?**

MMB, the company that introduced the Bt cotton seed, put out an announcement in the year 2009 that in four districts of Gujarat the company crop surveillance staff detected pink bollworm and on the basis of the observations of the crop surveillance staff the company came to the conclusion that the Bollworm had begun to develop resistance against Bt toxin. The company immediately released the second generation Bt seed. The second generation Bt seed had one more gene, Cry2Ab, inserted into the first generation Bt cotton seed in addition to Cry1Ac that was already engineered by a process called gene pyramiding. In this context, several
questions arise regarding the introduction of the second generation Bt cotton seed. The addition of Cry2Ab was based on company’s claim that in four districts of Gujarat the Bollworm developed resistance against Bt toxin. There was no independent study in Gujarat that corroborated the claim of the company. Neither was there evidence of resistance reported from Bt cotton growing other states. The article argues that it is quite likely that the introduction of the second generation Bt cotton seed is dictated by the corporate strategy to deliberately declare the first generation Bt seed obsolete and phase it out in the market although it still worked in many Bt cotton growing states in India.

The genetic engineering technology has ushered in new contractual relations among science, state, private enterprise, farmers and consumers on the basis of their interests and system of meanings held by these institutions and groups (Haribabu 2004). In other words, molecular breeding, in particular, and agricultural biotechnology, in general, are intricately related to the state, market and the civil society including framing communities and consumers. The state is expected to regulate the technology for its safety and in countries like India ensure that seed is available at affordable price. Farmers are interested in obtaining better quality seed at affordable price to ensure higher productivity. Consumers are interested in safe cotton. Further, consumers attach aesthetic meaning to cotton. Primary interest of the companies involved in the production of Bt cotton seed is to ensure profits and also protect its GM cotton seed from patent infringement. To ensure profits and control over the technology one of the strategies adopted by the companies is planned obsolescence. Extending the control over the proprietary technology through patents beyond the duration of the validity of the patent by making some changes to the patented product is ‘ever greening’ of patents.

**Planned Obsolescence in Seed Production**

The phrase ‘planned obsolescence’, first used by Bernard London, was popularised by Brooks Stevens in 1954. Manufacturing enterprises resort to strategies like building in obsolescence into the design, for example, automobiles, clothing, consumer electronics, etc. The motivation on the part of the firms to resort to planned obsolescence is to ensure long-term sales of products and profits there on by reducing the life cycle of the
products. Consequences of planned obsolescence for the users of the products are that they have to repeatedly buy the new products although old product may still be functional. In industry sometimes the manufacturers deliberately use inferior materials in making the product to shorten the life cycle of the product. This can be seen in the case of computer industry and fashion industry. As mentioned above, with the industrialisation of seed production seed industry also seem to employ the strategies employed by manufacturing industry to maintain their control over technology – design, utility, and price. Planned obsolescence in a sense is mass discarding of industrial products and releasing the waste into the environment. One has to deal with the disposal of the wastes discharged into the environment. Can one talk of planned obsolescence in seed production, as seed production involves organisms and environment? What are the implications of obsolescence in the production of transgenic seed for farming community, consumers and environment? Transgenic seed production is not the same as production of products with the use of inorganic materials. While safety is an important parameter in manufacturing any industrial product using inorganic materials, safety assumes added significance in the context of organic world as it involves long-term consequences for health of human beings and environment. What necessitates planned obsolescence in the context of transgenic seed production? For example, the terminator seed is an example of planned obsolescence as the seed is genetically modified to silence the gene(s) responsible for germination.

In the context of genetically modified cotton seed we should keep in mind that the host and pest co-evolve and the pest develops resistance against the toxin after sometime due to adaptation and mutation. This necessitates further improvement in the capacity of the plant to fight the pest through new genetic material. It is a continuous battle between the host and pest. Perhaps the company may have seen this as an opportunity to introduce the second generation Bt cotton seed (Bollgard II) even when the indications of pest resistance are not visible. In other words, the company that owns the Bt technology employed the strategy of planned obsolescence by introducing the second generation of Bt seed on the basis of the evidence provided by its own crop surveillance staff. In fact, in other states, where farmers were using first generation Bt seeds, farmers did not find pink Bollworm in the Bt cotton fields. Though the first generation Bt cotton seed still works in
providing resistance against Bollworm, the company stopped producing
the first generation Bt cotton. Even if the farmers want to use the first
generation Bt cotton seed it is not available in the market.3 The only seed
that is available is the second generation Bt cotton seed (Bollgard II).

Regulatory Issues
Biotechnology, as any other technology, is not risk-free. Hence it has to be
regulated from the point of view of safety especially regarding the risk it
poses to health of human beings and the environment. Another aspect of
regulation is the access to technology.

Farmers should have access to seed in terms of quantity, and quality and
affordability. In India over 50 per cent of farmers are small and marginal
farmers having less than 5 acres of land. An important aspect, the social
context in which Bt cotton is cultivated, is the agrarian relations in cotton
cultivation in states like Andhra Pradesh. Many of the small farmers are
also tenants who take land from owners on certain terms of sharing the
produce/income for a specified number of years. Further, Bt cotton has
been adopted by farmers practising agriculture in a variety of agro-climatic
zones, rain-fed areas, irrigated areas and different kinds of soils. The most
vulnerable farmers are the tenants who cultivate Bt cotton in rain-fed
areas as their cultural (in terms of knowledge about Bt technology) and
economic endowments (in terms of the degree of ability to raise resources
for cultivation) are limited. In fact tenant farmers cannot secure institutional
credit just because they do not have legal ownership title to the land they
are cultivating. One of the important requirements of cultivating Bt cotton
is refugia – refuge plantation, that is at least 20 to 25 per cent of the land
under Bt cotton has to be planted with conventional varieties of cotton
so that Bollworm would feed on the conventional cotton plants and thus
resistance of Bollworm against Bt toxin could be delayed. However, several
studies indicate that the farmers, especially small and marginal farmers,
are unwilling to spare 20-25 per cent of land under Bt cotton for refugia as
it would reduce total yield in a plot of land even in countries like the US.
Though 90 per cent said they complied with norms of year 2000 regarding
maintenance of refugia, only 71 per cent could accurately report the required
sizes and locations of refugia (Laxminarayan and Fischer 2004). Moreover,
the firm which has proprietary right over the seed may not be interested
in insisting on refugia if the firm has plans to make Bollgard I obsolete by introducing Bollgard II. In other words, it would replace Bollgard I. It is in this context, regulation becomes a necessity to ensure safety and access. One can conceive three models of regulation: a) market; b) government; and c) governance.

In the case of market model the market becomes a regulatory mechanism in the sense that the issues relating to safety, efficacy and access are determined by market. If the product does not satisfy the overall quality, the users would reject the product. The underlying assumption here is that the market is a perfect institution. In reality, it does not seem to be the case, especially in the changed institutional context knowledge production is getting increasingly concentrated in big multinational corporations and knowledge has become an intellectual property that can be accessed only at a cost.

In the case of the government model, term ‘Government’ is used to denote a mode of ordering society, where power rests in the hands of formal public institutions and the state. In this mode, regulation is accomplished through centralised means of exercising power, such as regulatory policies and laws. The model assumes that the government institutions have autonomy and independence to evaluate the issues relating to safety, and risks. The national governments across the world have developed a series of predictive methods (e.g., risk assessment, cost-benefit analysis, climate modelling) that are designed, on the whole, to facilitate management and control. This model generally gets extended even to areas of high uncertainty (Jasanoff 2003). These methods achieve their power through claims of objectivity and a disciplined approach to analysis. In the Indian context the government regulatory agencies – Genetic Engineering Approval Committee (GEAC) under the Ministry of Environment and Forests (MoEF) – recommended for the commercial release of Bt Brinjal (eggplant). The GEAC seems to argue that the recommendation is based on hard scientific data and objective analysis provided to the Committee by the company that developed the Bt Brinjal without independently evaluating the adequacy, relevance and reliability of evidence in support of Bt Brinjal for its effect on human health, environment and biodiversity relating to Brinjal. In the face of protests by civil society and its organisations the ministry imposed a moratorium on the commercial release of Bt Brinjal until it is evaluated and
certified for safety for human beings and environment. Another regulatory body that is concerned with conservation of biodiversity and access to genetic resources for research and development is the National Biodiversity Authority (NBA) established by the National Biodiversity Act of 2002. The NBA also does not seem to have evaluated consequences for diversity of Brinjal in the country. In India agriculture is a subject that is within the purview of the state governments. The state governments are expected to implement national policies formulated by the central government. This feature of the centre-state relations sometimes leads to variations in the implementation of a given policy. The New Agricultural Policy 2000, which aims at using biotechnology to improve agriculture, was formulated by the central government which the state governments are expected to implement.

In the case of Bt technology, risks have to be identified and evaluated to judge whether or not the risks are within acceptable limits in a given context. Judgement on acceptable level of risk is never based on purely scientific criteria. The judgement is an outcome of the interplay among competing and sometimes conflicting values (Barbour 1980). Another element in the judgement regarding safety and efficacy is the timeframe over which any technology is safe and efficacious. For example, what is the timeframe over which the Bt technology is safe for humans and environment and what is the timeframe over which it is efficacious in fighting the Bollworm as it develops resistance against the Bt toxin over time.

As mentioned earlier, in India over 50 per cent of farmers are small and marginal farmers, with average size of land holdings of less than five acres of land and tenants. They seem to place trust in the state agencies to address their problems relating to safety, efficacy and affordability.

It is in this context that the regulatory issues regarding the release of the second generation of Bt seed have to be examined. As mentioned earlier, it appears that the company after observing pink Bollworm in four districts (Amreli, Bhavnagar, Junagad and Rajkot) of Gujarat during its routine cop surveillance reported to the GEAC in 2009 crop season that pink Bollworm developed resistance against its genetically modified cotton seed Bollgard I. However, there is no evidence that the GEAC accorded approval on the basis of an independent survey of the incidence of pink Bollworm across the country and an independent assessment of safety of the second generation
Bt cotton seed as the seed has a new protein Cry2Ab in addition to Cry1Ac that has already been engineered into the cotton seed. The regulators seemed to have accepted the information and evidence submitted by the company regarding the development of resistance against Cry1Ac by pink bollworm and the efficacy of the second generation Bt seed with an additional protein, Cry2Ab without checking the veracity of the company’s claims. Stone (2011) in his study of Warangal Bt cotton farmers in 2008 found that none of the farmers understood that there were four versions of Bt to choose from or how they differed from one another.

The Indian Parliament constituted a committee on agriculture in 2009-10 with 31 members of the Parliament which interacted with several scientists, lawyers, industry representatives, journalists, civil society organisations and farmers. The Committee submitted its report entitled: ‘Cultivation of Genetically Modified Food Crops: Prospects and Effects’ in 2012. It observed that the bio-safety assessments made by the company that promotes transgenic crops are accepted by the Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Appraisal Committee (GEAC) for evaluating the transgenic crops. The Committee in its judgement concluded as follows (p.373):

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\text{The internal Bio-Safety Committee (of a company) functions and performs all basic assessments and evaluations of a transgenic product developed by that very company. It also generates data on the basis of which RCGM and GEAC base their evaluation, as stated previously in this report. This mechanism does not inspire confidence for obvious reasons.}
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The Committee also examined the implications of transgenic crops for biodiversity in India. The Committee observed (p.371):

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\text{The experience of the Country with Bt cotton shows that with the advent of transgenic variants and the initial hype surrounding it, the traditional cotton varieties have just been wiped out.}
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**Price Regulation**

The price of the first generation Bt cotton in the initial years of its release proved to be unaffordable to small and marginal farmers. Monsanto-Mayco Biotech (MMB), which controls Bt technology as mentioned above, priced the first generation Bt cotton hybrid seed in the initial years (2003-05) between Rs. 1600-1800 for 450 grams in contrast to Rs. 400-450 for
conventional hybrid seeds. Until 2006 the seed companies which obtained licence from MMB to use Bt trait were charged one-time license fee and royalty fee of Rs.1250 by MMB on every 450 grams packet of seed sold in the market. As the prices were unaffordable, farmers and civil society organisations in Andhra Pradesh protested against the exorbitant price of Bt cotton seed forcing the government of Andhra Pradesh to intervene to bring down the price of Bt cotton seed (Davuluri 2013). In January 2006, the government of Andhra Pradesh registered a case against MMB with the Monopolistic and Restrictive Trade Practices Commission (MRTPC) and argued that the price fixed by MMB tantamount to monopolistic trade practice. The MRTPC by making use of the provisions of the MRTP Act of the Government of India gave a ruling that MMB indeed indulged in monopolistic trade practice and ordered that the pricing of Bt cotton seed be reviewed by MMB. In response to the imposition of the provisions of the MRTP Act by the government of Andhra Pradesh on 11 May 2006, the company reduced the price of its Bt cotton seed (Bollgard-I) from Rs. 1600 for a packet of 450 gm to Rs. 1200. The government of Andhra Pradesh reasoned that the price was still high and unaffordable and in June 2006 issued an ordinance declaring a ceiling on the price of Bt cotton seeds at Rs. 650 for Bollgard I seed for a packet of 450 gm of seed (inclusive of technology fee). The other cotton growing states of India also followed the example of Andhra Pradesh and adopted the same pricing policy. In 2011 various state governments revised the price upwards by 30 per cent – for Bollgard I variety from Rs. 650 to Rs. 830 and for the second generation Bt seed (Bollgard II) variety from Rs. 750 to Rs. 930. In other words, in this model civil society vigilantism is an important aspect of the regulatory process.

**Governance Model**

Governance describes a change in the meaning of government (Rhodes 1996). Governance can be taken to imply that the development and control of science and technology is not simply a matter for government or ‘the state’ (Rose 1999: 16–17). Instead it is necessary to include the activities of a much wider range of actors—including industry, scientific organisations, public and pressure groups, consumers, and the market. The term governance refers to new constellations of power that go beyond the structures, rules
and processes of classical government. Governance often involves non-governmental actors in policy-relevant decision-making, which means that the boundaries between public and private sectors are increasingly blurred. With the involvement of these new actors in policy-making and decision-making constellations shift from the top-down model that is characteristic of government to network-shaped structures that exemplify governance (Stoker 1998).

The framing of policy issues and the processes of regulation and implementation are increasingly de-centralised in this model of ordering society. Thus, governance may be seen as a new mode of distributing power and regulatory competences. In this model, regulatory institutions are constituted in such a way that they are broad-based in their composition and more democratic in their functioning. It essentially means that the stakeholders get involved in the process of technology regulation. In this model, for instance, the need for the introduction of the second generation Bt seed would be discussed by the stakeholders in different regions to assess whether or not the second generation Bt seed is needed. Then Bt cotton growers in states, where there are no signs of pest resistance against Bollworm, would have the opportunity to indicate that they would continue to use the first generation Bt cotton seed as it is still effective in fighting the pest.

**Conclusion**

It appears that the company that produced the first generation Bt cotton seed anticipated the fact that the Bollworm would develop resistance against Bt toxin and was on the lookout for an opportunity to introduce the second generation Bt seed and only informed the regulatory body about introduction of the second generation Bt seed. However, the regulatory bodies have not conducted any independent study to evaluate the claims of the company before giving approval to the second generation Bt seed. The regulators accepted the information provided by the company. It is quite possible that the second generation Bt cotton seed was introduced after declaring the first generation Bt cotton seed obsolete with the twin objective of ever-greening the patent and to increase the price of the seed. Further, the company removed the first generation Bt cotton seed from the market even in states where the Bollworm has not developed resistance.
In the innovation literature planned obsolescence is seen as necessary force that drives innovation and economic growth. While this may hold well in the case of manufacturing of products with inorganic materials, can we say the same thing in the case of innovations that tend to transform the organic world? In the case of genetic transformation of organisms the set of actors that are involved are different: industry, non-human organic world and social and cultural world of humans. The capacity of the organisms to adapt and mutate, as in the case of Bollworm that the company claims to have developed resistance against I generation Bt toxin, throw up several challenges: R&D, regulatory, ethical and environmental challenges. Hence, the policymaking and regulatory processes that are concerned with technological innovations in transforming organic world must be broad-based and democratic. A broad-based and democratic stakeholder participation in regulation and in making judgements over ethical issues is an imperative to promote inclusive and sustainable development.

Endnotes

2. Brooks Stevens, an American design engineer, in 1954 used the phrase as the title of his talk. He defined planned obsolescence as: ‘instilling in the buyer the desire to own something newer and, little better, a little sooner than is necessary’. From consumers’ point of view they are made to buy newer products even though the old product still works thus making them spend money to acquire the later version of the same product. See ‘Planned Obsolescence: A Weapon, of Mass Discarding, or a Catalyst for Progress? Available at: http://paristechreview.com/2013/09/27/planned-obsolescence/
3. In the month of July13 we carried out Focus Group Discussions (FGD) in two villages of Guntur district as part of a preliminary study of the farmers’ experience regarding the second generation Bt cotton seed. The farmers mentioned that they did not observe any pink Bollworms in their fields earlier and now they are using the second generation seed. They also mentioned that the first generation Bt cotton seed is not available in the market now. The farmers we interacted with in Guntur district did not plant refugia. They argued that devoting 20-25 per cent of the land under Bt cotton for refugia would reduce their returns. In other words, they argued that if they plant Bt cotton in the whole area they would get higher returns.

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A Co-Dynamic Model to Frame Controversies Over Genetically Modified Crops in India

Asheesh Navneet*

Abstract: The article talks about the current controversy around the GM crops in India. The focus has been to understand and analyse the basis of the political discourse taking shape either in favour or against the use of GM technology in India. The theoretical framework of the study has been drawn in line with the Advocacy Coalition Framework (ACF) theory developed by Sabatier and Jenkins-Smith. The ACF theory describes about how changes can be seen in a particular society with the coming or arising of new issue and new political identities getting recognised. Apart from agricultural production there are other concerns related to GM technology like health, environment and ownership rights. Several of these concerned issues further exacerbate the political conflict among various stakeholders. To study the reason for all the existing political conflicting debate, an approach in the form of co-dynamic model has been adopted in the article to understand the circumstances in which arguments are shaped by the stakeholders.

Keywords: GM Technology, Advocacy Coalition Framework (ACF) theory, Co-Dynamic model, Technocratic Model, Red Book Model, Stakeholders.

Introduction
The promotion of GM technology in Indian agricultural system is one of the most contentious issues today. The parliamentary bill in the form of Biotechnology Regulatory Authority of India (BRAI) has lapsed. The BRAI bill was developed by the Ministry of Science and Technology under the Department of Biotechnology (DBT) in the year 2009. The bill is the second

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version of the previous bill which was called the National Biotechnology Regulatory Authority (NBRA) developed by the same ministry. The bill was formed in the light of the recommendations given by task force committee formed by the agriculture ministry in the year 2003. It was the task force committee headed by Dr. M. S. Swaminathan that had recommended the formation of independent authority for biotechnology regulation (Karihaloo and Kumar 2009) after the illegal cultivation of Bt cotton by Gujarat farmers came into light (Lianchawii 2005). The recent development in the area has been that amidst protest, the Ministry of Environment and Forest (MoEF) under the NDA government through the body of Genetically Engineering Appraisal Committee (GEAC) has granted approval for field trials of at least 13 GM crops including mustard, cotton, brinjal, rice and chickpea. GEAC is a statutory body for recommending approval to any release of genetically-engineered products into the environment. The move has been taken by the government despite recommendations given by the Parliamentary Standing Committee and the Supreme Court appointed Technical Expert Committee (TEC) to put moratorium on the field trials of GM technology in India for infinite period of time until the concerns of whether GM food crops are safe to humans and animals and their other environmental impacts are not adequately assessed and addressed.1

Since the agriculture is a state subject, so it is up to the state governments to either welcome GM technology in their respective states or to restrict it. It has been observed that most of the Indian state governments have not allowed field trials for GM food crops including Gujarat where the success story of Bt cotton has been so well known. Recently, Maharashtra has granted no-objection certificate (NOC) to the biotech companies to conduct field trials of some biotech crops like rice, chickpea, maize, brinjal and cotton according to the media reports. The decision in Maharashtra was taken by the state-level committee headed by Anil Kakodar, the former chairperson of Atomic Energy Commission. According to the committee, the trials would be carried out in the confined plots of one hectare or less. The results of the field trials would be strongly monitored before the state takes any further step towards its cultivation. While the Supreme Court says that there is no ban on cultivation of GM crops, it has ruled that permission for cultivation and trials has to be taken by the state governments. However, the biotech companies want this clause to be removed. Maharashtra has now become
the fourth state after Punjab, Delhi and Andhra Pradesh to give approval for open field-trials of GM crops. Gujarat, Rajasthan, Madhya Pradesh, Chhattisgarh, Haryana, Bihar, West Bengal, Orissa, Tamil Nadu and Kerala have rejected such trials.

With all these happenings around, the political conflict is explicitly visible among the different stakeholders who are either for or against the use of GM technology in Indian agricultural farms. The aim of this article is to analyse the reason for the basis of these political conflicts among stakeholders. For that, the questions that the article aims to address are: Who are the different stakeholders involved in the political conflict of GM technology in India and what are the priorities of these stakeholders on the basis of which their demands are different from each other?

These are the two broader questions which this article would be dealing with the help of Advocacy Coalition Framework (ACF) theory developed by Sabatier and Jenkins-Smith. The ACF theory broadly explains about the way in which political conflict is taking shape because of arrival or arising of any new particular issue and how players or stakeholders look to influence the policy matter in this regard. In other words, the aim of ACF is to understand the political hurdles that come in the way for the adequate utilisation of GM technology, the matter is a burning issue and the interests of state, civil society and the corporate sectors are at stake.

**The Advocacy Coalition Framework (ACF) Theory**

The ACF theory has been developed by Sabatier and Jenkins-Smith. The theory can be understood at three levels, i.e. ‘macro’, ‘micro’ and ‘meso’ levels which are considered to be the three foundation stones. A flow diagram of ACF theory (Figure 1) can help in understanding these three essential levels.

**Policy Subsystem and External Factors (Macro Level)**

The theory assumes that policymaking in the modern society is a highly complex process and therefore representatives of any stakeholders or interest groups must specialise in the area they intend to influence. According to Sabatier and Weible (2007), any subsystem is characterised by both territorial (e.g., civil society) and functional (e.g., policymaking bodies) dimension. The policymaking participants include not only the ‘traditional
iron triangle’ of legislators, bureaucrats and judiciary, but also researchers and journalists who are specialised in the policy area. The theory further assumes that policy participants hold strong beliefs and are motivated to translate those beliefs into actual policy. Their beliefs are assumed to be strong and stable and this makes the major policy change within the system difficult (Sabatier and Weible 2007).

According to Sabatier and Weible (2007), in developing countries many subsystems are quite nascent because of the instability of the broader political system and lack of trained personnel in the subsystem. They argue that majority of policymaking occurs within policy subsystems where specialists are involved in negotiations. However, the behaviour of most of the policy participants in the subsystem is mainly affected by two sets of exogenous factors, in which one is fairly stable and the other is quite dynamic (see Figure 1). The relatively stable parameters include basic attribute of the problem, distribution of natural resources, basic constitutional structure and fundamental socio-cultural values and structure. These parameters rarely change within periods of decade or so, thus rarely providing impetus for policy change within a policy subsystem. On the other hand, the dynamic external factors include changes in socio-economic conditions, changes in the governing coalitions, and policy decisions from other subsystems. The ACF hypothesises that change in at least one of these dynamic factors is a necessary condition for a major policy change.

**The Individual Model and Belief Systems (Micro Level)**

At this level, the developers of ACF theory intend to show how this theory is different from rational choice theory. In general, the rational choice theory assumes self-interested actors rationally pursuing relatively simple material interests. However, the ACF theory assumes that normative beliefs must be empirically ascertained and therefore does not exclude the possibility of a priori altruistic behaviour. But ACF does stress on the difficulty of changing the normative beliefs among policy actors. According to this theory, each policy actor or participant see the world through a set of perceptual filters composed of preexisting beliefs that are difficult to alter. Therefore, it can be argued that actors from different coalitions are likely to perceive the same information in very different ways, leading to distrust.
Figure 1: The ACF Flow Diagram

Relatively Stable Parameters
1. Basic attributes of the problem.
2. Basic distribution of the natural resources.
3. Fundamental socio-cultural values and social structure
4. Basic constitutional structures (Rules)

External (System) Events
1. Change in socio-economic conditions.
2. Changes in public opinion.
4. Policy decisions and impacts from other subsystems.

Long Term Coalition Opportunity Structures
1. Degree of consensus needed for major policy change.
2. Openness of the political system.

Short term constraints and resources of subsystem actors.

Policy Subsystem
Coalition A Policy Brokers Coalition B
a. Policy beliefs
b. Resources
Strategy
reguidance instruments

Decisions by Governmental Authorities
Institutional Rules, Resource Allocation, and Appointments
Policy Outputs
Policy Impacts

The ACF also borrows a key proposition from the “prospect theory” developed by Quattrone and Tversky in 1988 (Sabatier and Weible 2007). According to them, actors value losses more than gains. Drawing implications from here, the ACF argues that individuals remember defeats more than victories. These propositions further interact to produce “devil shift” which means tendency for actors to view their opponents as less trustworthy and more evil and powerful than they probably are. As a result this increases the density of ties among members within the same coalitions and exacerbates conflict across competing coalitions. It has also been taken into account by ACF theory that perceptual filters of individual actors or interest groups tend to throw away all dissonant information and accept only conforming information which further strengthen their beliefs thus making the belief change more difficult. Therefore, this individual model of ACF is well suited to explain the escalation and continuation of policy conflict.

**Advocacy Coalitions**

According to the ACF, the behaviour and beliefs of any stakeholder are shaped by the particular society or particular groups that they belong to. For example, if any individual is a member of farming community or civil society groups like Navdanya or Gene Campaign, or medical scientists concerned for health related issue, or environment groups like Greenpeace concerned for environment, then their beliefs and behaviour will be shaped accordingly. When the stakeholders belonging to these many groups and societies carrying different beliefs become policy participants, they naturally tend to influence the policymaking processes. The ACF assumes that policy participants strive to translate the elements of their beliefs into actual policy before their opponents can do the same. Therefore, in order to have any prospect of success, they seek to form allies, share resources, and develop complementary strategies. The “devil shift” exacerbates fear of losing to opponents, thus motivating actors to align and cooperate with allies. The ACF has argued that policy participants would generally seek allies with people who hold similar beliefs among legislators, agency officials, interest group leaders, judges, researchers, and intellectuals from multiple levels of government. Further, to form advocacy coalition, some degree of non-trivial coordination is required among allies of policy participants. The ACF further shows that advocacy coalition provides the most useful tool to aggregate
the behaviour of hundreds of organisations and individuals involved in a policy subsystem over a period of a decade or more.

**Political Controversy around GM Technology**

The issue of GM technology became more contentious in India after the Bt cotton was approved for commercial cultivation in the year 2002. This move of the Government of India (GOI) led to the different political stand either for or against the GM technology. With the help of advocacy coalition framework (ACF), the political controversy behind the GM crop technology can be analysed. Based on Figure 1, a contextualised Figure 2 is given.

The crux of Sabatier and Jenkins-Smith’s advocacy coalition framework (ACF) theory is that formation of coalition takes place among different interest groups either in favour or against particular issue in order to affect policy formation in future. In the above case, flow diagram represents the changing situations due to the introduction of new GM technology from different society. Before the introduction of this technology there was an existing system in accordance with the conventional forms of practices in case of agriculture. Suddenly when GM technology gets introduced, several concerns like health, environment and ownership related issues are also raised apart from the benefits from this technology. The issue gives rise to a new political discourse between the proponents and opponents of GM technology and the new political identities are recognised in terms of associations with the formation of new coalitions. The coalitions are formed on the basis of similar beliefs about the new GM technology among different stakeholders. The stakeholders can be biotechnology-scientists, medical scientists, farmers, environmentalists, business groups, etc. The priorities of the different stakeholders are different. For example, the priority for a medical scientist can be related to health concerns which can be different from the priority of plant-biotechnology scientists whose priority can be to enable plants or crops to grow in adverse weather conditions by manipulating their genes in labs. Similarly, the priority for the environmentalists would be to preserve the biodiversity. So based on different priorities the demands raised by these stakeholders would be different and thus give rise to discourse on how to deal with GM technology and whether this technology can be shaped in accordance with the different voices related to the priorities of stakeholders. The different voices and concerns need not result in a stand-off or adversarial position always.
Figure 2: The Flow Diagram of Policy-process of GM Technology-based on ACF Theory

Source: Conceptual Framework developed by author based on Sabatier and Weible (2007).
Keeping the above argument in mind, four coalitions have been identified in the Indian context, which are either in support or against the use of GM technology in agricultural production. These coalitions can be categorised in the Table 1.

**Table 1: Possible Conditions on GM Technologies in India**

<table>
<thead>
<tr>
<th>Coalitions formed to support GM Technology</th>
<th>Coalition formed to oppose GM Technology</th>
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Source: Prepared by the author.

In Figure 2, two coalitions, viz. coalition A and coalition B have been shown. Coalition A is in favour of GM technology and coalition B is anti-GM technology. The civil society groups who belong to coalition A are Shetkari Sanghatana, Punjab Agricultural University (PAU) Kisan Club, Naujawan Kisan Club, Nagarjuna Rythu Samakhya, and Pratapa Rudra Farmers Mutually Aided Coop Credit and Marketing Federation. All these organisations are among the leading farmer-organisations that are led by Consortium of Indian Farmers Association (CIFA) to protest against the recommendations of a Supreme Court appointed Technical Expert Committee (TEC) to put moratorium on field trials of GM crops, arguing that the farmer communities need biotechnology to increase the agricultural production.

Apart from these civil society groups, there are also some corporate sector groups like Mahyco-Monsanto, Advanta, Kaveri Seed, Dhanuka Agritech, etc., that favour government’s decision to allow field trials of some 200 transgenic varieties of GM seeds. With this move of the Indian government, biotechnology companies have become ready for big investment plans on research and development (R&D). In order to promote GM technology, biotech industries have formed an association called Association of Biotech-led Enterprises (ABLE), in which biotech companies like Monsanto and Advanta are active members.
The science academies have mostly been in favour of using the GM technology for Indian agriculture. Most of the plant biotechnology scientists of government institutes like Centre for Cellular and Molecular Biology (CCMB), Hyderabad; National Bureau of Plant Genetic Resources (NBPGR) of Indian Council of Agricultural Research (ICAR), New Delhi; International Centre for Genetic Engineering and Biotechnology (ICGEB), New Delhi; National Institute of Plant Genome Research (NIPGR), New Delhi believe that GM technology has the potential to increase the agriculture production specially of those conventional crops that show less production or of those varieties which are on the verge of extinction. The technology has the potential to enable crops to grow even in adverse weather conditions; for example, there are some GM crops like maize that have been designed in lab to increase their tolerance level so that they can stand for longer time in drought regions. Therefore, according to the scientists of these institutes, the GM technology has the immense potentialities but till date their various potentialities have not been realised because of several hurdles like protest against the field trials of GM crops by anti-GM activists.

On the other side, there are also some civil society groups like Gene Campaign, Navdanya, Greenpeace, Andhra Pradesh Vyavasaya Vruthidarula Union (APVVU), Shaswat Sheti Kriti Parishad (SSKP), Thana (an environmental organisation in Kerala), CREATE and FEDCOT (consumer rights groups), etc., who are showing their protest against the move of Government of India to promote GM technology in India. Some civil societies like non-governmental organisations (NGOs) and farmers’ organisations have come together to form an association called “Coalition for GM-Free-India”. The ‘Coalition for GM-Free-India’ is a loose and informal network of scores of organisations and individuals from across India, campaigning and advocating to keep India GM-free, and to shift the farming towards a sustainable path. Therefore, consisting of farmers, consumers, environmentalists, women and other organisations, this network is opposed to the environmental release of genetically modified organisms (GMOs). Similarly, the Alliance for Sustainable and Holistic Agriculture (ASHA) is an alliance of hundreds of organisations and individuals including numerous farmers groups from more than 20 states of India and works on promoting sustainable agriculture and sustainable farm livelihoods.
Both these coalitions which are either for or against GM crop technology are trying to influence Indian government in policy-making process. The tension over the issue has been observed mainly between the Ministry of Environment and Forest (MoEF) and Ministry of Agriculture (MoA). The Genetic Engineering Appraisal Committee (GEAC) is a statutory body which has the responsibility to take the final call on whether GM crops have to be grown on Indian farms or not, and falls under the ambit of MoEF. It has been observed that the approach of MoEF office under different ministers has been fluctuating. When Jairam Ramesh and Jayanthi Natarajan were in the office, they were apprehensive of giving approval to field trials to the GM food crops and the moratorium on GM crops was imposed in the year 2010. But later when Veerappa Moily in UPA’s term and Prakash Javdekar in NDA’s term came in the office, they removed all kinds of restrictions by approving GM crops for field trials. As of now in the year 2015, there is no tension between MoEF, MoA and the Ministry of Science and Technology (MoS&T) and all these ministries have arrived at a common decision to approve GM crops for field trials to see whether they can help in increasing the agricultural production in India.

In India, agriculture is a subject that lies in the state list under Schedule 7, with reference to the Article 246 of Indian Constitution. Therefore, the central government cannot alone decide over the matter of GM crops and the state governments too have to actively play the role in this regard. Figure 2 the flow diagram, which is based on ACF theory, explicitly shows that if the system has to be transparent and open, then opinions of state governments as well as media and oppositions would also have to be taken into account.

The ACF flow diagram strives to explain the formation of new political identities and stands either in the form to support or oppose GM technology. However, the theory lacks in explaining the basic reason for the formation of this stand. It does explain Maarten Hajer’s argument that policymaking often takes place in a context where fixed political identities and stable communities are assumed and policy interventions can make people aware of what they feel attached to by influencing people’s sense of collective identity, i.e. the awareness of what unites them and what separates them from each other (Hajer 2003). However, it does not reflect much on the question why new stands and identities are formed and what are the priorities of individuals or group of individuals who recognise themselves with these new identities.
Therefore, to fulfill this limitation of the ACF theory, an approach in the form of “Co-Dynamic Model” has been adopted to understand the different priorities of various interest groups involved in either supporting or opposing the GM technology. Hence, the very purpose of using co-dynamic model is to study in detail one particular aspect of ACF theory which shows that in case of GM technology two kinds of coalitions taking shape, Coalition A and Coalition B: A supporting GM technology and B opposing it and thus influencing the policymaking bodies of the government through various regulatory channels like the Review Committee on Genetic Manipulation (RCGM) and GEAC.7

The co-dynamic model has been developed by Millstone (Millstone 2014). In order to understand the importance and reliability of this model, it would be necessary to understand ‘the technocratic model’ and ‘the red book model’ which represent the positivistic and scientific approach towards policymaking processes (Millstone 2014). Through these models Millstone has only attempted to analyse the reason for the conflict over the issue of GM technology in a given society. According to him, if a scientist favours GM technology then he or she is looking for the solution of a specific problem related to agricultural yield which would be different from those who are looking from the point of view of biodiversity or environment or health or ownership related issues. With the help of this argument of Millstone, the purpose of this article is to analyse the priorities of the four coalitions: CIFA, ABLE, Coalition for GM free India and ASHA that intend them either to support or oppose GM technology. Therefore, the three specific models that are analysed here are: the Technocratic Model; the Red Book Model; and the Co-Dynamic Model.

**The Technocratic Model**
The scientific expertise in policymaking emerged in the work of two positivists named Saint Simon and Comte in the 19th century in France. They portrayed scientific knowledge sufficient for policymaking and their work later came to be known as a ‘technocratic model’ (Millstone 2014). The model has appealed to the scientific expert advisors because it has helped them in giving narrative to depoliticise the controversial policy issues and has further attributed high status to their knowledge, expertise and influence.
According to this model, the scientific facts are self-sufficient in determining the policy-decision making. The advocates of this model deem scientific approach to be appropriate in bringing progress by shaping more accurate and adequate policies. They consider that policymaking should be based on ‘sound science’. The implication of this model is that the responsibility of policy decisions should rely on technical and scientific experts and the different ministries of the government should confine themselves in taking advices from these experts.

The Red Book Model

The Red Book model is simply an improvised form of the technocratic model. This model is a two-stage process model in which the first part is dealt as the ‘risk assessment’ part and the second one as the ‘risk management’ part.

Among these two stages, i.e. the risk assessment and the risk management, the first stage is deemed to be purely scientific stage and the
second stage is a policymaking stage which has to deal with non-scientific and often normative considerations such as economic, social and political factors. In this two-stage model, the policymakers who are also considered to be the ‘risk managers’ are well informed and influenced by the scientific advisors. The important fact to be noticed here is that the scientific advisory bodies are portrayed in this case as entirely free from all kinds of influences from non-scientific elements. As shown in Figure 4, this model is linear and unidirectional. It means that the scientific advisory body would be in a position to influence the policymaking governing bodies and the scientific advisory body would be free and independent from any influences and biasness and therefore their decisions would be taken seriously to shape policies by the governing bodies. The model was first outlined in a report, ‘Risk Assessment in the Federal Government: Managing the Process’, drafted by the US National Research Council (NRC) in 1983. Because of the colour of its cover the report came to be known as the Red Book (Millstone 2014).

**Critique of the Technocratic and Red Book Models**

According to Millstone, despite the official popularity of these models, they have been severely criticised by science policy analysts and sociologists of scientific knowledge. Both technocratic and red book models presuppose that the available scientific knowledge is reliable with full certainty and all experts can easily reach to consensus through it which is immensely false and baseless argument. In reality the available science is many a time incomplete, ambiguous and uncertain and therefore scientific communities have rarely been observed speaking with one voice.

Secondly, these models also presuppose that scientific assessments of risks and benefits can be achieved in highly neutral settings free from politics, social and cultural ethics. However, numerous scholars have already demonstrated several ways in which political, social, economic and cultural considerations have influenced the agendas, deliberations, and conclusions of certain official scientific advices.

**A Co-Dynamic Linear Bi-Directional Model**

In order to solve the difficulties found in above models, a co-dynamic linear bi-directional model is derived. Like the previous two models, this model
is also linear but unlike them, its starting point is not scientific facts and assessments but a set of normative judgements about what is more important and priority wise which policy-aim and objective should be pursued. Secondly, unlike the previous two models, this model is not unidirectional but bidirectional and it is characterised by the reciprocal interactions.

**Figure 5: A Co-dynamic Model**

![Co-dynamic Model Diagram](image)

*Source: Millstone (2014).*

According to Millstone, this model assumes that science based technology policymaking relies both on expert scientific assessments and non-scientific considerations. Instead of portraying risk assessment occurring in a policy-free space, the model represents the scientific deliberations to be sandwiched between two sets of judgements. The first set of judgement guides what is to be assessed and thus to seek scientific answers of the particular questions. In the second set of judgement, appropriate actions are thought of in the light of scientific answers including comparisons with other alternative courses of action along with acceptability of affordable costs and benefits.

With the help of co-dynamic model, Millstone explains how different groups of scientific risk assessors reach different conclusions. According to him, the reason to reach different conclusion and derive different answer is that the assessors have asked and answered altogether different questions and on that basis, reviewed different sets of data. This has further given rise to the political conflict among different groups and stakeholders.
The co-dynamic model along with other two models, i.e. technocratic and red book model, can be taken and operationalised to understand the political controversy surrounding the GM crops in India. The description of the other two models, i.e. the technocratic and the red book models on which the co-dynamic model is built on, simply enhances the importance of co-dynamic model, making it more feasible for a democratic society where different voices of stakeholders are taken into consideration in the policymaking process. Therefore, this article mainly focuses on the co-dynamic model through which the controversy around the GM technology in Indian society is being analysed to understand the priorities of different stakeholders either supporting or opposing the GM technology.

Analysis of Policy Debate on GM Crops in India

Significance of Cotton Cultivation

Cotton is considered to be one of the most important cash crops in India and it has played significant role in contributing to the growth of national economy. Agricultural scientists have estimated that India holds the world’s largest area under cotton cultivation, i.e. it represents 20-25 per cent of the total global area (Gruere, Mehta-Bhatt and Sengupta 2008). It ranks third in terms of cotton production and falls behind only China and the US in the line (Gruere, Mehta-Bhatt and Sengupta 2008). Despite this, the yield per hectare of cotton in India has been among the lowest in the world until recently (Gruere, Mehta-Bhatt and Sengupta 2008).

According to Supriya Pal, India has been recognised as the cradle of cotton industry for over 3000 years (i.e. from 1500 BC to 1700 AD). The Indian farmers have been historically involved in growing some of the finest cotton fabric since time immemorial. According to Pal, the textile industry has contributed about 14 per cent of industrial production, 4 per cent of GDP, and has provided direct employment to over 33 million people (Pal 2010). Therefore, cotton is the basic requirement of the Indian textile industry. Pal further reports in his article that cotton cultivation engages around six million farmers to fulfill the need and consumption capacity of the textile industries. These facts are considered to be the prime reasons why certain corporate industries along with the state governments started campaigning for the technological solutions that can help in increasing the cotton yield.
In this regard, GM crop in the form of Bt cotton was seen as a new technology to enter the agricultural market and fields. In the year 2002, Indian regulatory bodies like the Review Committee on Genetic Manipulation (RCGM) and Genetic Engineering Appraisal Committee (GEAC) approved three hybrid varieties of the Bt cotton. They are MECH 12, MECH 162, and MECH 184. All of them were developed by the Maharashtra Hybrid Seed Company (Mahyco). Mahyco had a licensing agreement with Monsanto to backcross the Cry1AC Bt gene with the conventional cotton breeds. According to Qaim et al. (2006), during the first year of commercial adoption of GM cottons in India, GM hybrids were grown on about 90,000 acres. In the year 2003-2004, almost 250,000 acres of land was used for Bt cotton cultivation (Qaim et al. 2006). In the year 2004, a fourth Bt cotton hybrid was developed by Rasi seeds and was subsequently commercially approved for cultivation. The area used for its cultivation was estimated to be around 1.3 million acres, which is equivalent to about 7 per cent of the total national cotton area (Qaim et al. 2006). In addition there is a sizeable black market too for unapproved Bt cotton seeds.

**Clashes of Opinions**

Monsanto in its “Sustainability and Corporate Responsibility Report - 2010” views that demands for foods, clothes and houses are growing at a greater pace in the present era, but their supplies from basic resources are not growing at all significantly at the required pace; in fact they tend to be stagnant. Today farmers need to get more from every acre of land, every drop of water and every unit of energy. The report argues that to bring sustainable agriculture in all parts of the world is the prime motive of the Monsanto team and they are committed to develop such technologies that can enable farmers to produce more while conserving more of the natural resources at the same time that are essential for the success. The report states that Monsanto is going to fulfill its commitment by introducing certain seeds and traits developed by using the applications of biotechnology in the agricultural sector. Today India has become one of the world’s leading adopters of new cotton technologies. Monsanto’s 2010 annual report states that because of the coming of the new Bollgard II technology, higher cotton yields have increased the incomes of some Indian farmers and enabled them to purchase more hectares of land (Monsanto 2010).
The Asia-Pacific Consortium on Agricultural Biotechnology (APCoAB) and Asia-Pacific Association of Agricultural Research Institutions (APAARI) together published a report on “Bt Cotton in India”. The report says that due to the adoption of Bt cotton, the Indian cotton production scenario has changed dramatically. The Bt cotton has helped farmers in increasing their cotton production and enabled India to become one of the major countries in the world exporting cotton to other countries. The report further points that the area under Bt cotton has reached 7.6 million hectares in the year 2008-09, thus constituting nearly 81 per cent of the total cotton area in India (Karihaloo and Kumar 2009). As a result, the net cotton production has reached to a record of 4.9 million tonnes (Karihaloo and Kumar 2009).

Even the government official data show that there has been an immense increase in the yield per hectare of the cotton production with the adoption of Bt cotton by the Indian farmers. Before the year 2002 when Bt cotton was still not approved for commercial cultivation, one can see the decline of yield per hectare of cotton production (Directorate of Economics and Statistics 2012). Therefore, according to the official data Bt cotton has been a revolution that helped farmers in increasing their incomes.

However, there have also been critics who through their survey report have shown contrasting picture of Bt cotton effect in India. According to them, this particular technology has brought no good for Indian farmers (Sahai and Rahman 2003). In their report they compared Bt 162 and Bt 184 belonging to Mahyco-Monsanto with those of local non-Bt cotton varieties such as ‘Brahma’ and ‘Banny’. In their investigation they found that Bt cotton is of shorter duration, i.e. 90 to 100 days, while non-Bt cotton’s life was found to be of longer duration, i.e. 100-120 days. Bt cotton comparatively showed less vigorous growth and they had fewer branches and their leaves were smaller in size. One of its major problems was its premature dropping of bolls.

While on the other hand, the number of bolls in the non-Bt variety was found to be much higher. One of the major finding of Sahai and Rahman’s study was that the current variety of Bt cotton in India does not offer any protection against the Pink Bollworm (Pectinophora gossypiella) (Sahai and Rahman 2003). Therefore, Sahai and Rahman’s major concern is that Bt cotton does not provide complete protection to the plant from its pests and so more testing is required.
On a similar note, Dinesh C. Sharma in “India Today” has reported that the ongoing debate on GM crops has taken a new turn when the American seed firm Monsanto accepted the fact that cotton pest, viz. pink bollworm has developed resistance to the Bt cotton variety in Gujarat (Sharma 2010). According to the Monsanto spokesperson, resistance is natural and quite well expected. The company has put the blame of pink bollworm resistance to the early use of unapproved Bt cotton seeds by farmers and also their refusal to do refuge planting8 (Sharma 2010). Therefore, in order to tackle the problem of pink bollworm attack on plants, Monsanto introduced the second generation of Bollgard II variety in the year 2006 which contained two proteins, viz. Cry1AC and Cry2Ab.

But this revelation has not surprised the Environment Action Groups like Greenpeace, Navdanya and Gene Campaign. According to them, this has been the pattern Monsanto has been following since long. Once Bollgard 1 fails, they would then start pushing for Bollgard 2 and recommend farmers to apply refuge planting and to maintain that refuge area farmers will have to apply pesticides which ultimately is going to increase the input costs. Also it has been observed that Bt cotton has created several new pests, and to control them farmers are using 13 times more pesticides than they were using prior to the introduction of Bt cotton (Shiva 2012).

Vandana Shiva in her writing has argued that the shift from the saved seed to the corporate monopoly of the seed supply represents a shift from biodiversity to monoculture in agriculture. According to her, in 1998 the World Bank made some structural adjustment in its policies and forced India to open up its seed sector to the global corporations like Cargill, Monsanto, and Syngenta. In this way, farm seeds in India started getting replaced by corporate seeds, which need fertilisers and pesticides and are difficult to save or many a times cannot be saved at all for next season. Beside that corporations also managed to prevent seed savings through patent rights and by engineering the seeds with non-renewable traits (Shiva 2012). As a result farmers or peasants are compelled to buy new seeds for every planting season. So the argument here is that seeds which were earlier deemed to be free resources for farmers have now taken a shape of commodity which has caused new expenses and led to the increase in poverty and indebtedness in a country like India.
The other concern for environmentalists is that monoculture and uniformity have increased the risks of crop failures. This is because the diverse seeds adapted to diverse ecosystems are gradually getting replaced by the rushed introduction of uniform and often untested seeds into the market.

P. Chengal Reddy, who is the president of Federation of Farmers Associations (FFA) in Andhra Pradesh (AP), has expressed his distress at the growing number of environmental NGOs in India which preach through their private publications and popular media about what Indian farmers should do and should not do. He has argued that since these environmental NGOs are composed of non-agriculturist members, they do not know anything about the Indian agriculture and their talks and written articles rarely relate to the Indian realities of farms. He is critical of environmentalist’s concern for Indian biodiversity. For him the biodiversity and food production need not and in fact do not go together. Therefore, according to Reddy, the job of the farming community is to produce more foodgrains and other allied items to meet the requirements of rapidly growing population.

David and Sai (2002) in their survey report have shown that around 30 per cent of farmers in the region of Warangal and Khammam districts of the Telangana state are ready to cultivate cotton only in the condition that they are able to receive its suitable price in the market. Their survey report shows that none of the farmers in these two regions were found opposed to Bt cotton cultivation on technical grounds (David and Sai 2002). Their survey report shows that farmers are not much bothered about the long term consequences of Bt cotton planting. Their prime concern is to make profit (Herring 2006), and for that they can easily be persuaded by some corporate or government agents (David and Sai 2002).

Glenn Davis Stone has criticised how pro-industry agricultural leaders and proponents of Bt cotton cultivation insist that farmers should be left with their own wisdom and choice in the matter to select the modern technology. According to him, this kind of argument ignores several social aspects which are involved and play role in the agricultural decision making. For him, any information that we directly perceive from the environment is known to be the “Payoff Information” (Stone 2004). The payoff information is initially raw and requires interpretation through discussions and sharing
among the community members. Another important aspect which needs to be comprehended according to Stone is that every human individual try to adapt according to their environment as well as their social groupings. Therefore, external world for any individual would be not less than any bundle of contradictions and among this bundle of contradictions any individual is capable of acquiring only certain selective ideas and beliefs and the method to acquire these beliefs and ideas is simply based on ‘rules of thumb’ with the further biases (Stone 2004). Based on this argument, Stone has argued that when Warangal farmers were asked during survey about what influenced them to go for Bt cotton cultivation, their reply was not the ubiquitous ‘good yield’ but they routinely recalled that since other farmers were growing them so they also followed (Stone 2007).

In India Bt cotton is the only GM crop that has been extensively grown by the farmers. Apart from Bt cotton, other GM crops like rice, maize, chickpea and brinjal are still in the pipeline to get approval and their field trials are in the process. According to the government official report (Directorate of Economics and Statistics 2012), after the introduction of Bt cotton, the cotton production in the country has increased immensely. However, some civil society organisations like Greenpeace, Gene Campaign, Navdanya and members of coalition called ASHA and Coalition for GM-Free-India have been raising allegations against GM technology that Bt cotton helps in protecting cotton against the bollworm only for few years, after that the bollworm becomes resistant to the Bt cotton and thereafter Bt cotton is ineffective to the bollworms. As a result farmers have to spray more chemical pesticides to protect the cotton which ultimately increases the total input costs of farmers in growing cotton.

However, the plant-biotechnology scientists argue that GM technology can help farmers in their agriculture production only for certain period of time. After that the technology becomes outdated and needs to be replaced with the newer version of GM technology that will again benefit the farmers for certain period of time. Therefore, according to the plant-biotechnology scientists, one particular form of GM technology cannot be the permanent solution for the agriculture and after certain period of time that particular GM technology needs to be replaced by the newer version of it. For the rapid growth of agriculture, farmers need GM technology and the scientists are constantly working in that direction.
Conclusion
The ACF theory along with the Millstone’s Co-dynamic model is useful in understanding the complexities of GM crops in India. The ACF theory talks about the formation of new groups in the form of coalitions with the coming up of new issues. The GM technology in this case has become a new issue of division of opinions among stakeholders because it is a new technology for the Indian society. The article recognises the formation of four coalitions with the coming up of GM technology in India. These four coalitions are: CIFA and ABLE in support of GM technology on one hand and Coalition for GM-free-India and ASHA protesting against the use of GM technology on the other hand. Within these four different coalitions numerous groups of stakeholders are involved.

The ACF theory basically explains the basis for the formation of coalitions and further incorporates the propositions of other theories like “prospect theory” developed by Quattrone and Tversky in 1988 (Sabatier and Weible 2007), which talks about actors valuing losses more than gain. These propositions further interact to produce “devil shift” which means tendency for actors to view their opponents as less trustworthy and more evil and powerful than they probably are. As a result this increases the density of ties among members within the same coalition and exacerbates the conflict across the competing coalitions. Therefore, with this kind of argument, the ACF theory does provide the basis for the existing political conflict among coalitions either supporting or opposing for the particular cause but it does not provide any reason for supporting or opposing that particular cause.

From the ACF framework, one can very well understand the exacerbating political conflict among the given four coalitions. But one also needs to understand the basic reason for supporting and opposing the GM technology by the stakeholders involved in these coalitions. As already explained in the article, the stakeholders of GM technology are not only scientists, farmers and corporate companies like Monsanto, but also consumer groups like CREATE and FEDCOT and civil society groups like Navdanya and Gene Campaign. Therefore, for the development of effective policy for the democratic society like India, voices of all the stakeholders are important and need to be considered. Millstone’s Co-dynamic model
very well explains the reason for the existence of various conflicting voices of the stakeholders on the issue of GM technology. According to Millstone, the reason for arriving at different conclusion on GM crop by them is not because they are providing different interpretations of agreed and shared bodies of evidence, but because they have asked and answered different questions, and therefore reviewed different data sets.

Stakeholders have several priorities in the form of agricultural production, health, environment and ownership rights and on that basis they are raising demands to influence the policymaking which is still in the process in case of GM technology. So the development of effective social policy in a democratic society like India, which can be agreeable to every party, is challenging and more time should be devoted in understanding the priorities of all stakeholders and accordingly use the benefits of GM technology for agriculture with a strict regulatory channel in place.

Endnotes

1 The Parliamentary Standing Committee on agriculture was formed in the fifteenth Lok Sabha. The committee formed its fifty ninth report in the year 2013-2014 dealing with “cultivation of genetically modified food crops – prospects and effects”. The committee was headed by Shri Basudeb Acharia.

Similarly, the Technical Expert Committee (TEC) came into force by the order of the honourable Supreme Court dated 10 May 2012 in writ petition (civil) No. 260 of 2005, Aruna Rodrigues and others vs. Union of India.

2 Shetkari Sanghatana is a non-political union of farmers formed with the aim to create freedom of access to markets and technology by farmers. It was founded by Sharad Anantrao Joshi in the late 1970s.

Similarly, Punjab Agricultural University (PAU) Kisan Club was started by Dr. T. S. Sohal in 1966 in Barewal village near Punjab Agricultural University. Like Shetkari Sanghatana PAU Club is also a non-political, non-profit organisation of progressive farmers of the state. Similarly, Naujawan Kisan Club is a non-political and non-profit organisation based in Punjab and Karnail Singh is its president. Nagarjuna Rythu Samakhya and Pratapa Rudra Farmers Mutually Aided Cooperative Credit and Marketing Federation are other two non-profit organisations for farmers based in Andhra Pradesh and Telangana regions, respectively.

3 CIFA was launched in March in the year 2000 at Tirupathi by the leader of farmers Shri Sharadh Joshi. Presently, it is functioning under the direction of Shri P. Chengal Reddy. CIFA is basically a coalition of different small organisations of farmers that work to enable Indian farmers to get access to modern technologies that can help them in increasing their farm production and also get direct access to the market.

4 Based on interviews conducted by the author with the scientists of the mentioned biotechnology institutes.
Gene Campaign is a research and advocacy organisation dedicated to food and livelihood security of rural and adivasi communities and rights of farmers and local communities. It works with communities in villages as well as at policy-making levels to ensure rights of farmers and local communities over their biodiversity and indigenous knowledge. Gene Campaign was set up in 1933 by Dr. Suman Sahai and a group of scientists, environmentalists and economists who were alarmed by the impact of international developments on the genetic resources of the developing world and livelihood security of rural and tribal communities that depend on them.

Navdanya started as a programme of the Research Foundation for Science, Technology and Ecology (RFSTE), a participatory research initiative founded by the world-renowned scientist and environmentalist Dr. Vandana Shiva, to provide direction and support to the environmental activism. The main aim of Navdanya biodiversity conservation programme is to support local farmers, rescue and conserve crops and plants that are being pushed to extinction and make them available through direct marketing.

Greenpeace India has been working on various issues related to the environment since 2001. It is a non-profit organisation, with presence in 40 countries across Europe, the Americas, Asia and the Pacific. Their work in India is focused on four broad campaigns, viz. stop climate change, sustainable agriculture, preserving the oceans and preventing another nuclear catastrophe.

Andhra Pradesh Vyavasaya Vruthidarula Union (APVVU) is a federation of unions of agricultural workers, marginal farmers, fisherfolk and rural workers in Andhra Pradesh. It was established in 1991.

Shashwat Sheti Kriti Parishad (SSKP) is a farmers’ organisation promoted by Yuva Rural Association (YRA). The organisation has been taking up local issues such as availability of water and seeds. SSKP has also shown its protest against genetically-modified organisms (GMOs).

There is not much difference between the word alliance and coalition in terms of meaning, however alliance represents stronger group in terms of working together to achieve the specific goal.

Both RCGM and GEAC are the two important Indian biosafety regulatory bodies involved in the process of granting approval to the GMOs. RCGM is an important body of the Department of Biotechnology (DBT) which falls under the ambit of the Ministry of Science and Technology. Similarly, GEAC falls under the Ministry of Environment and Forests (MoEF). RCGM mainly oversees researches on GMOs whereas GEAC is responsible for the approval of activities involving large-scale use of GMOs and their release into the environment through experimental field trials.

Fields with Bt. crops are required to provide refuge areas to help control resistance. The refuge area provides an environment for non-mutant insects which can mate with possible resistant insects to produce non-resistant insects. Here Bt. crops are planted with alternating rows of regular local non-Bt. crops. So the insects that have developed resistance to Bt. have more chances to mate with insects that have not developed resistance to Bt. Therefore, by the laws of genetics, the progenies produced will be insects without any resistance to Bt.
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Cotton being an important cash crop of India plays a significant role in the country’s industrial and agricultural economy. The introduction of Bt cotton has apparently reduced the dose of plant protection chemicals. This has been responsible for virtual spread of Bt cotton on more than 90 per cent of the cotton area. Globally, India ranked second in cotton production and first in exports. These, however, have been at the cost of negative impacts threatening the sustainability issues in Bt cotton. This book edited by Lalitha and Vishwanathan has articles from scholars, focusing on the development and diffusion of Bt technology in India.

Introduction has the overview of development of agri-biotechnology industry, with experiences of Bt-cotton. With the gradual acquisition of seed companies by mega agro-chemical companies since late 1980s, the plant biotechnology sector began consolidating its position. The big companies strengthened their position by cross licensing the relevant technologies. Institutional innovations leading to the establishment of the Department of Biotechnology (DBT) in 1986 under the Ministry of Science and Technology and the liberalisation of seed policies complemented the development of biotechnology sector. Thus, the bio-agri share in the total biotech sector increased from 4.6 per cent in 2002 to an impressive 14.9 per cent in 2011.

Cotton is vulnerable to a large number of insect pests, important being the cotton bollworm which can cause losses up to 60 per cent. The innovations in plant biotechnology aimed at this pest to reduce crop losses and thereby improve profitability. After thorough experimentation across the country, Bt cotton was allowed by the Government of India in 2002 using three genetically modified hybrids. The adoption of Bt cotton resulted in
shift in area, production and productivity from 7.63 million ha, 137 lakh bales, 321kgs/ha, respectively in 2003 to 11.1 million ha, 335 lakh bales, and 518kgs/ha, respectively in 2010. This chapter highlights the importance of public and private institutions in the development of cotton industry along with the research issues in Bt cotton addressed in the volume.

In chapter second, Kumar has highlighted the status of cotton development and the role of public research institutions in cotton research and development. The process of seed production, maintenance and distribution, contribution of the public sector in developing Bt cotton and conventional varieties and their production technology is discussed in detail. The contribution of public sector research in Bt cotton is claimed to be minimal and is yet to be diffused. In future, the area under cotton is likely to increase due to the increasing demand from the burgeoning population. However, this cannot happen at the expense of food security as claimed. Nevertheless a judicious blend of modern technology and traditional wisdom is crucial for the conservation of natural resource quality.

In the next chapter, Indira throws light on the importance of regulatory system in authorising promotion and adoption of Bt technology. This chapter sets the context of the biosafety regulatory system and the institutional framework evolved over time. The phenomenal growth in the adoption of Bt cotton lead to the biosafety regulations. However, there are shortcomings for complete acceptance and implementation of biosafety regulatory measures. The author highlights the efforts to improve the existing regulatory system which requires strengthening of the extension services that caters to the needs of the farmers. The author does not discuss the accountability and responsibility of the private sector largely responsible for Bt cotton in extension efforts, as the extension efforts are largely with the public sector, and whether the private sector corresponded and took the public sector in confidence in the process of research and development of Bt technology which also includes the diffusion of innovations. Parallelly there has been continuing and growing debate over the sustainability of GM crops.

The chapter by Ashok, Uma, Prahadeeswaran and Jeyanthi analysed the economic and environmental impacts of Bt cotton using the field data from 480 cotton farmers (80 Bt and 40 conventional) from each of the four states of Maharashtra, Andhra Pradesh, Gujarat and Tamil Nadu.
Using appropriate statistical methods the authors demonstrated higher profitability of Bt cotton over the conventional check and established that reduced pesticide cost is largely responsible for the same. Decomposing the source of higher productivity, the results revealed that 17 per cent and 15 per cent of the contribution have been from Bt technology and increased use of inputs, respectively. The study has reported that the environmental impact quotient was significantly lower for Bt cotton farmers due to reduced pesticide consumption.

The need to consider the risk and technological uncertainty in the assessment of Bt cotton technology is emphasised in the fifth chapter by Gaurav and Mishra. They have used mixed-methods framework combining two cross sectional surveys and ethnographic inquires in Gujarat and Maharashtra for 2009 and compared with the unit level data from a nationally representative sample for 2002-03. Empirical evidence presented shows that Bt cotton was associated with increasing risk in a drought year as confirmed by the results of the mixed-methods approach. The level of risk in Bt technology is evident as 65 per cent of the India’s cotton is produced in rain-fed lands.

Anchal Arora and Sangeeta Bansal examined the impact of price controls on diffusion of Bt cotton and profitability of seed providers. Authors used panel data from nine cotton growing states from 2002-08. Price controls positively contributed to the diffusion of Bt cotton technology and increasing the revenues of seed providers in the short run. Impact of price controls on profitability depends on the cost conditions of providing Bt cotton seeds. Authors suggested encouraging competition in seed market by supporting research and development by local gene providers and indigenous research by farmer scientists. These will reduce cotton seed prices further as also the market imperfections in cotton seed markets.

Chapter seven by Lalitha and Vishwanathan analysed the process of selection and use of seeds and pesticides using the two cotton farmers surveys (2007-08 and 2010-11) and one dealers survey (2007-08) in Gujarat. Farmers’ preferences of seed varieties depend on proven (time-tested) record. The analysis shows that the small and large farmers have adopted newer seeds more than the medium farmers. The intensity of plant protection spraying by all size groups of farmers was relatively higher in the
initial months of plant growth. Analysis further revealed that costs towards pesticides have remained high in spite of reduced use of pesticides. This could be attributed to control of sucking pests, expensive pesticides and farmers who most often mix chemicals that alter the composition, leading to the pest resurgence requiring furthermore sprays. In order to overcome these problems, extension efforts are necessary to reach the farmers regarding appropriate chemicals application. Once again here the mismatch between technology and extension between the private sector, which generated the technology, and the public sector, which provides extension, has been highlighted.

Kamal Vatta and Sidhu examined the economic scarcity and physical scarcity of labour in cotton production. The cost of labour use increased by 65 per cent in 2009 as compared to 2004 and this was largely due to sharp increase in the real and monetary wages. It is estimated that in 2009-10, there was a demand for 66.4 million labour days in cotton, and medium and large farmers were relatively more vulnerable to the rising wage rates. Cotton picking (55 per cent) and manual weeding (27 per cent) accounted for the major share of labour use and the extent of shortages for these activities varied between 20 per cent and 35 per cent. Authors suggested to promote mechanisation to address the problems associated with physical and economic scarcity of labour in cotton cultivation.

The ninth chapter by Vishwanathan and Lalitha elaborately reviewed the dynamics of development and diffusion of Bt cotton technology in the context of ecosystem management. The comparative performance of farmers who adopted Bt cotton along with the IPM/IRM is compared with non-adopters. Experiences of Bt cotton in Maharashtra, Punjab and Andhra Pradesh revealed negligible rate of Bt cotton adoption with IPM/IRM and hence emphasised the need for greater extension support system than the present. Study of contradictions in Bt cotton adoption in cotton growing countries in the US revealed that the Bt technology has been strictly regulated with regard to compliance of IPM/IRM and the refuge management practices, which is not the case in India. Hence, the authors strongly felt the need for evolving and revamping institutional interventions for sustainable outcomes in the post-Bt period.
The concluding chapter by the editors discussed the future state of affairs of agri-biotechnology and concluded with inspiring message that “no technology would be 100 per cent safe and therefore safety guidelines need to be drawn and strictly adhered to”.

This book has a little focus on economic analysis of long-term impacts and sustainability issues of Bt cotton. In addition, editing could have been more effective avoiding repetition of facts in successive chapters. Nevertheless, this book is a valuable addition to the literature on Bt technology in India in the backdrop of the debate on the Bt technology and introduction of new Bt crops, for rich economic analysis, substantive findings and policy implications. This work is of immense value for researchers, students, civil society and policymakers on the role of Bt technology in cotton.

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Socio-economic impact assessment of GM crops is necessary to understand impacts of their diffusion and for decision making regarding their cultivation in different areas. Social scientists have done many studies on socio-economic impact of GM crops and literature is expanding on a good note in the context of evaluation of technological efficiency of GM crops through field trials and analysis of data from these trials. In case of India, as Bt cotton is the only approved GM crop for cultivation, it is no wonder that it has attracted many studies. Over the last decade as the acreage under Bt cotton increased, new issues like pest resistance and prices of GM seeds became contentious. This book analyses the socio-economic impact of Bt cotton in India, that is, the Bt-cotton production improves the farm yields, increasing the incomes of small and large farmers, which directly helps in improving their livelihood. It also analyses the negative aspects of the Bt-cotton like ecological sustainability and economic advantage for small farmers in the long run.

Chapter 1 of the book introduces topics such as spatial and temporal analysis of the world cotton production; trends in area, production, yields and farm input use in cotton in India; cost of cultivation and net return analysis of Bt cotton in different states; factors influencing Bt cotton yields; effects of income from Bt cotton on health, sanitation, education and other livelihood status, labour employment and income of landless farmers; and perception of farmers about various positive and negative aspects of Bt cotton cultivation.

In Chapter 2 authors bring out the spatial and temporal analysis of international cotton production, trends of its trade and position of India in
comparison with world. It is noticed that the contribution of cotton in India’s agro-export, both in value and quantity terms, has grown significantly. In the post-Bt cotton period India’s cotton exports to various countries have increased and imports have declined due to rapid expansion of domestic cotton industry.

Chapter 3 focuses on the trends in area, production and yields, input usage and prices of cotton in India. In the post-Bt-cotton period there is a quantum leap in growth rates which shows huge influence of Bt-cotton on farming choices in India, although it creates instability in the context of area of production and yield due to marginal lands, erratic weather conditions and increase in attacks by pest. If we focus on the trends in cotton prices it is seen that the average Minimum Support Prices (MSP) and Farm Harvest Prices have increased with the increase in production. The usage of pesticides as well as cost of pesticides as proportion of total production cost have shown a declining trend in the post-Bt-cotton period due to reduction of pest control cost and effectiveness of Bt technology. The usage of fertiliser, irrigation, human and machine labour have shown an incremental trend while seed usage and pesticide usage and their costs compared to the total cost have shown a decremental trend.

Economics of cultivation of Bt cotton like distribution area, output of Bt cotton, irrigated area under cotton production, cost of production, etc., based on a field survey undertaken in 2011-12, are presented in Chapter 4. The area share under Bt cotton relative to total cotton area was comparatively higher than the non-Bt cotton area. For the year 2011-12 the yields of Bt cotton are slightly higher than non-Bt cotton; main reason for this being more area coming under Bt cotton cultivation. To analyse the cost of cultivation of Bt cotton the total cost of working capital, seed, fertiliser, micronutrients, growth regulators, farmyard manure, pesticide, irrigation, farm mechanisation and human labour have to be considered.

Chapter 5 focuses on factors influencing Bt Cotton yields. The authors use production function based on Cobb Douglas method (Log Linear) to find out the contribution of a particular input in the total agricultural productivity. For this purpose per hectare gross value of output of Bt cotton productivity has been regressed on net cultivated area, per hectare seed, fertiliser, farmyard manure, growth regulator, pesticide, irrigation, human labour and
machine labour costs. According to analysis of the study, it was seen that per hectare costs of fertilisers, micronutrients, pesticides, irrigation, and mechanisation have a positive impact on productivity of Bt cotton whereas net cultivated area, per hectare cost of seed, growth regulators and labour costs have a negative impact relationship with the productivity of Bt cotton.

Chapter 6 depicts farmer’s perception on the impact of Bt Cotton on income, health and livelihood status. It also considers yields, returns, seed usage, expenditure, pesticide usage, pest attacks, human health, livestock health, soil quality and suicides of farmers in the context of cotton production. The quantity of seed usage per hectare in Bt cotton is less than that used in non-Bt cotton, although expenditure is higher in Bt cotton and it is similar across all surveyed districts and different farm size categories. Farmers wanted to get higher yields and earn higher income on maximum areas in short term which created problem for the small farmers because the large farmers extracted the lion’s share of the profit from the Bt-cotton technology, compared to the small farmers, that is, large farmers took most of the advantage from gain relative to the small farmers due to their capacity and resources. Small farmers faced more risk by devoting the entire area to Bt cotton production to get maximum benefits due to lack of facilities. There are certain other reasons also in the context of farmers’ suicides, such as insufficient rainfall, lack of irrigation, ineffective pest control, lower crop yields due to soil moisture stress, low and fluctuating cotton prices over the years, and non-availability of credit in time specially to the small farmers. Non-availability of labourers during cotton picking season created problems as labour cost had been rising. Still it was found that farmers got high return and earned more income from Bt cotton which helped them to spend more on their other livelihood indicators such as family health care, education, recreation, etc.

Chapter 7 shows the impact of Bt cotton on labour employment and income of landless labourers. It depicts that after commercial cultivation of Bt cotton, human labour use has increased compared to the pre-Bt cotton period, both in terms of man days per hectare and growth rates. Labour availability became a great problem in the areas studied due to Mahatma Gandhi National Rural Employment Guarantee Act (MNREGA) scheme which provided 100 days of guaranteed work during the year. This
coinciding with the cotton picking season pushes the labour cost upwards as labourers have options to earn. Recently, the income gap between male and female labourers has come down and this helps the landless labourers to increase their standard of living.

**Some of the key findings of this book are:**

- India might use Integrated Pest Management (IPM) in cotton production and this should be integrated as part of Bt cotton cultivation strategy.
- The high cost of Bt seeds creates disincentive for the small and marginal farmers. Hence, the issues related to monopoly pricing and seed production and pricing deserve closer attention by policymakers.
- Development of varieties, that are suitable for different agro-climatic conditions and agro-ecological areas, should be undertaken and the question of pest resistance and management of different types of pests should also be considered. If the public and private sectors can collaborate in developing varieties to meet the needs of farmers cultivating cotton in different agro-climatic conditions, that will ensure wider diffusion of Bt technology.
- Overall socio-economic impact of the Bt cotton during the past ten years has been positive and significant. But this should not result in complacency and Bt cotton should not be seen as a magic bullet.

The book has presented some significant issues related to socio-economic impact of Bt-cotton in India and thus it is a welcome addition to the literature on studying the socio-economic impacts of Bt-cotton in India.

—Payel Chatterjee
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